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 SECURITIES AND EXCHANGE COMMISSION  
 WASHINGTON, D.C. 20549  
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FORM 10-K  
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ANNUAL REPORT  
 PURSUANT TO SECTION 13 OR 15(d)  
 OF THE SECURITIES EXCHANGE ACT OF 1934

FOR THE FISCAL YEAR ENDED  
 DECEMBER 31, 2000

COMMISSION FILE NUMBER  
 0-23490

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 VIVUS INC.  
 (EXACT NAME OF REGISTRANT AS SPECIFIED IN ITS CHARTER)

DELAWARE  
 (STATE OR OTHER JURISDICTION OF INCORPORATION  
 OR  
 ORGANIZATION)

94-3136179  
 (IRS EMPLOYER IDENTIFICATION NUMBER)

1172 CASTRO STREET, MOUNTAIN VIEW, CALIFORNIA 94040  
 (ADDRESS OF PRINCIPAL EXECUTIVE OFFICES AND ZIP CODE)

(650) 934-5200  
 (REGISTRANT'S TELEPHONE NUMBER, INCLUDING AREA CODE)  
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SECURITIES REGISTERED PURSUANT TO SECTION 12(b) OF THE ACT: NONE

SECURITIES REGISTERED PURSUANT TO SECTION 12(g) OF THE ACT:

COMMON STOCK, \$.001 PAR VALUE

PREFERRED SHARE PURCHASE RIGHTS  
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Indicate by check mark whether the Registrant (1) has filed all reports required to be filed by Section 13 or 15(d) of the Securities Exchange Act of 1934 during the preceding 12 months (or for such shorter period that the Registrant was required to file such reports), and (2) has been subject to such filing requirements for the past 90 days. Yes  No

Indicate by check mark if disclosure of delinquent filers pursuant to Item 405 of Regulation S-K is not contained herein, and will not be contained, to the best of Registrant's knowledge, in definitive proxy or information statements incorporated by reference in Part III of this Form 10-K or any amendment to this Form 10-K.

As of March 9, 2001, the aggregate market value of the voting stock held by non-affiliates of the Registrant was \$140,211,860 (based upon the closing sales price of such stock as reported by The Nasdaq Stock Market on such date). Shares of Common Stock held by each officer, director, and holder of 5 percent or more of the outstanding Common Stock on that date have been excluded in that such persons may be deemed to be affiliates. This determination of affiliate status is not necessarily a conclusive determination for other purposes.

As of March 9, 2001, the number of outstanding shares of the Registrant's Common Stock was 32,479,640.

DOCUMENTS INCORPORATED BY REFERENCE

Certain information required by Items 10, 11, 12 and 13 of Part III of Form 10-K is incorporated by reference from the Registrant's proxy statement for the 2001 Annual Stockholders' Meeting (the "Proxy Statement"), which will be filed with the Securities and Exchange Commission within 120 days after the close of the Registrant's fiscal year ended December 31, 2000.

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## VIVUS, INC.

## FISCAL 2000 FORM 10-K

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This Form 10-K contains "forward-looking" statements about future financial results, future products and other events that have not yet occurred. For example, statements like we "expect," we "anticipate" or we "believe" are forward-looking statements. Investors should be aware that actual results may differ materially from our expressed expectations because of risks and uncertainties about the future. We will not necessarily update the information in this Form 10-K if any forward-looking statement later turns out to be inaccurate. Details about risks affecting various aspects of our business are discussed throughout this Form 10-K. Investors should read all of these risks carefully, and should pay particular attention to risks affecting the following areas: new product development and uncertainty of product approvals (pages 10 and 11); intense competition (page 11); future capital needs and uncertainty of additional financing (pages 11 and 12); limited sales and marketing in the U.S. (page 12); dependence on third parties (pages 12 and 13); raw materials (page 13); single manufacturing facility (page 13); and other risk factors as stated (pages 10 through 18).

## PART I

### ITEM 1. BUSINESS

#### COMPANY OVERVIEW

VIVUS, Inc. ("VIVUS" or the "Company") is a pharmaceutical company incorporated in 1991. The Company is engaged in developing, acquiring and marketing innovative products to improve quality of life disorders in men and women, with a focus on sexual dysfunction. The Company developed and markets in the U.S. MUSE(R) (alprostadil) and ACTIS(R), two innovations in the treatment of erectile dysfunction ("ED") and has entered into a license and supply agreement with Abbott Laboratories ("Abbott") (NYSE:ABT) for the international marketing and distribution of its male transurethral ED products. In Canada, VIVUS has entered into a license and supply agreement with Paladin Labs, Inc. ("Paladin") (TSE:PLB) to market and distribute MUSE. VIVUS has ongoing research and development ("R&D") programs in male ED, female sexual dysfunction ("FSD"), and male premature ejaculation ("PE"). Adding to the Company's R&D pipeline in the first quarter 2001, VIVUS licensed from TANABE SEIYAKU CO, LTD. ("TANABE"), a leading Japanese pharmaceutical company, TANABE's proprietary phosphodiesterase type 5 (PDE5) inhibitor compound TA-1790 for the oral and local treatment of male and female sexual dysfunction. In January 2001, the Company began enrolling patients in a multi-center clinical study for its FSD product, ALISTA(TM), intended to evaluate the sexual response in women with a primary diagnosis of Female Sexual Arousal Disorder ("FSAD").

During 2001, the Company will focus its R&D efforts on clinical development programs for FSD, PE and an oral treatment of ED using TA-1790. In addition, the Company will continue to evaluate the acquisition of new technologies and the development of strategic partnerships with other companies.

#### VIVUS STRATEGY

The Company's objective is to become a global leader in the development and commercialization of innovative therapies for the treatment of sexual dysfunction and other urologic disorders in men and women. The Company is pursuing this objective through the following strategies:

##### Targeted Research and Development (R&D) Efforts

The Company will exploit its expertise and patent portfolio by focusing its R&D activities on sexual dysfunction, premature ejaculation and other urologic disorders.

##### Focus on Development

The Company will continue to focus its efforts on clinical development of its R&D pipeline, targeted acquisitions of new technology and the development of new patentable uses of known pharmacologic agents for which significant safety data already exists.

## Maintain Proprietary Technology

The Company will continue to invest in building its patent portfolio. Currently, VIVUS has been awarded 13 patents and has 12 patent applications pending in the U.S. The Company also has 3 patents granted and 22 patents pending internationally. In addition, the Company has obtained exclusive worldwide rights to 53 patents in the fields of FSD and ED.

## Marketing and Distribution Strategy

VIVUS has entered into a license and supply agreement with Abbott to internationally market and distribute its current product MUSE and its second-generation product for the treatment for ED, ALIBRA(R), pending regulatory approval. In addition, Abbott has the option to co-develop and license future VIVUS transurethral products for the treatment of ED. In Canada, the Company has entered into a distribution and supply agreement with Paladin to market and distribute MUSE. The Company will continue to evaluate distribution, marketing, licensing and other opportunities for its products, as well as out-licensing rights related to products in its R&D pipeline.

## 2000 HIGHLIGHTS

### First Quarter 2000

The Company reported net income of \$1.5 million, for \$0.05 per diluted share. The Company strengthened its balance sheet, increasing cash by \$2 million to \$42.4 million while reducing total liabilities by \$5.2 million from December 31, 1999.

The Company further solidified its FSD intellectual property position through an agreement with AndroSolutions, Inc., whereby VIVUS has exclusive global rights to develop and commercialize FSD technologies based on the combined intellectual property pool.

The Company was awarded two new patents by the U.S. Patent & Trademark Office. The first provides the Company with broad patent protection for commercializing locally delivered PDE5 inhibitors, including combinations with other active agents, for the treatment of ED. The second provides VIVUS with broad patent protection for oral, topical, transdermal and transurethral administration of serotonin antagonists, specifically 5-HT3 antagonists, to treat PE in men.

### Second quarter 2000

The Company reported net income of \$890 thousand, for \$0.03 per diluted share. Cash and available-for-sale securities increased \$1.1 million to \$43.5 million from March 31, 2000.

The Company and Janssen Pharmaceutica International ("Janssen") agreed to terminate the distribution agreement for MUSE that was entered into in 1997.

The Company signed a license and supply agreement granting Abbott exclusive rights for MUSE covering all international markets outside the U.S. and Canada. In addition, this agreement provides Abbott with the exclusive right to distribute and market ALIBRA, pending regulatory approval, in all international markets outside the U.S. as well as the option to co-develop and license future VIVUS transurethral products for the treatment of ED in this territory.

The Company was added to the list of companies included in the Russell 2000(R) Small-Cap U.S. Equity Index, which is widely used as a benchmark for both passive and active investment strategies.

### Third Quarter 2000

The Company reported net income of \$208 thousand, for \$0.01 per diluted share. Cash and available-for-sale securities at September 30, 2000 increased \$700 thousand to \$44.2 million from June 30, 2000.

The Company filed an Investigational New Drug ("IND") application with the Food and Drug Administration ("FDA") for its FSD product, ALISTA, and began enrollment for the initial clinical study in October 2000.

The Company manufactured and shipped MUSE to Abbott within three months of the license and supply agreement being signed. Abbott began marketing and distributing MUSE in the United Kingdom in September, with distribution in Sweden and Germany occurring shortly thereafter.

The Company was awarded a new patent by the U.S. Patent & Trademark Office. This patent provides VIVUS with broad patent protection for commercializing local delivery of PDE4 inhibitors, including combinations with other active agents, for the treatment of ED.

The Company announced the appointment of John W. Dietrich, Ph.D. to the position of Vice President of Research and Development. Dr. Dietrich brings 20 years of experience in the pharmaceutical industry to VIVUS. During his career, he has coordinated and directed the discovery and development efforts for a variety of drug candidates. Most recently, Dr. Dietrich was Vice President of Research and Development at Cellegy Pharmaceuticals. In addition, Guy Marsh was appointed to the position of Vice President of Operations and General Manager. Mr. Marsh joined VIVUS in May 1998 as Senior Director of Operations, and has been instrumental in streamlining the Company's operations and cost-cutting efforts.

#### Fourth Quarter 2000

The Company reported net income of \$5.0 million, earning \$0.15 per diluted share. At year end, cash, cash equivalents and available-for-sale securities had increased \$4.9 million from December 31, 1999, while total liabilities had decreased \$8.3 million during the same period.

VIVUS began enrolling patients in the initial study of its FSD product, ALISTA.

Paladin was granted exclusive distribution and marketing rights for MUSE in Canada.

The Company was awarded a new patent by the U.S. Patent & Trademark Office, which provides broad patent protection for commercializing local delivery of PDE3 inhibitors for the treatment of ED.

The Company received 510(k) clearance from the FDA for over-the-counter (OTC) marketing of ACTIS, an adjustable constriction band used to improve erections in men with ED. FDA clearance for prescription use of ACTIS was obtained in 1996 and the device was introduced into the marketplace in 1997.

In October 2000, VIVUS withdrew its U.S. New Drug Application ("NDA") for its second-generation product, ALIBRA, a urethral microsuppository containing alprostadil and prazosin hydrochloride for the treatment of ED. The Company met with the FDA in December 2000 to determine what additional data is required to obtain marketing clearance for ALIBRA. The Company's communication with the FDA is ongoing regarding the requirements for approval of ALIBRA.

#### RESEARCH & DEVELOPMENT

VIVUS' objective is to be a global leader in the development and commercialization of innovative therapies for the treatment of sexual dysfunction and other urologic disorders. Currently, the Company has development projects in ED, FSD and PE. The Company has in-licensed a drug candidate and is developing new uses for well-known pharmacologic agents for which significant safety data already exists. The Company has a significant patent portfolio that it believes provides broad protection for the drug products under development. The Company will continually assess the feasibility and relevance of its current and future R&D projects, as determined by the Company's management and Board of Directors.

## DEVELOPMENT PROJECTS CURRENTLY INCLUDE:

DEVELOPMENT AREA -----	PRODUCT/TECHNOLOGY -----	STATUS -----
Male Erectile Dysfunction	ALIBRA	NDA withdrawn(1)
Female Sexual Dysfunction	ALISTA	Clinical
Male Erectile Dysfunction	TA-1790, Oral	Clinical(2)
Male Premature Ejaculation	Oral	Clinical
Male Erectile Dysfunction	TA-1790, Transurethral	Pre-clinical
Female Sexual Dysfunction	TA-1790, Topical & Oral	Pre-clinical

(1) The Company has met with the FDA and EMEA and continues to communicate with these agencies to determine what data is required to obtain marketing authorization for ALIBRA.

(2) Initial clinical evaluation of TA-1790 has been conducted by TANABE. Future clinical studies will be conducted by VIVUS.

## CLINICAL STUDIES

Clinical trial activity at VIVUS is currently focused on the development of ALISTA for the treatment of female sexual arousal disorder, the development of TA-1790 for the treatment of male erectile dysfunction, and the evaluation of formulations to be used as therapy for the treatment of premature ejaculation.

During the first quarter of 2001, a double-blind, placebo-controlled phase I safety evaluation of ALISTA was completed. The Company also initiated a double-blind, placebo-controlled, multi-center study to evaluate the efficacy of ALISTA in women with FSAD. Results from these studies are expected to provide data that will enable the Company to design and initiate larger-scale Phase II and Phase III studies required to obtain regulatory approval for this product.

The Company has licensed from TANABE TA-1790 for the treatment of sexual dysfunction in men and women. TANABE has conducted an initial phase I study evaluating the safety of TA-1790. In this study, healthy male volunteers received single doses of TA-1790. The Company plans initially to undertake additional clinical studies to evaluate the safety and efficacy of this compound as an on-demand oral therapy for the treatment of male erectile dysfunction. In addition, TA-1790 is being evaluated for its potential for use as a transurethral therapy for ED either alone or in combination with other vasodilators, and as an oral or topical treatment for FSAD.

In a proof of concept study completed during the first half of 2000, the effect of on-demand therapy with several classes of compounds for the treatment of premature ejaculation was evaluated. This study demonstrated statistically significant effects on ejaculatory latency, and additional formulation work to optimize the drug product for this indication is ongoing. The Company anticipates resuming clinical studies once this formulation work has been completed.

## SALES AND MARKETING

## Domestic

The Company supports MUSE sales in the U.S. with a small sales team comprised of regional sales managers and telesales personnel calling on targeted physicians. The Company participates in national urologic and sexual dysfunction forums and conferences such as the American Urologic Association annual meeting and the International Society for Impotence Research. In addition, the Company supports the ongoing research and clinical investigation of MUSE and the publication of data in peer-reviewed journals.

## International

The Company signed an international distribution and marketing agreement with Abbott in June 2000. Abbott purchases MUSE from the Company for resale in all markets except the U.S. and Canada. As of

March 2001, Abbott has re-launched MUSE in the United Kingdom, Ireland, Sweden, Switzerland, Denmark, Germany, New Zealand, Australia, Norway and Finland.

In November of 2000, VIVUS granted Paladin the exclusive rights to distribute and market MUSE in Canada; initial shipments of MUSE were made in the first quarter 2001 to Paladin.

#### VIVUS' TRANSURETHRAL SYSTEM FOR ERECTION

**Administration.** Administration of the transurethral system for erection is an easy and painless procedure. The end of the applicator is less than half the diameter of a man's urine stream and is inserted approximately three centimeters into the urethra. To use the transurethral system for erection, a patient urinates, shakes the penis to remove excess urine, inserts the transurethral system for erection into the urethra, releases the medication, and then massages the penis between the hands for 10 seconds to distribute the medication.

The application process takes less than a minute. Once administered, the pharmacologic agent dissolves in the small amount of urine that remains in the urethra, is absorbed across the urethral mucosa, and is transferred via local vasculature to the tissues of the erectile bodies. When successful, an erection is produced within 15 minutes of administration and lasts approximately 30 - 60 minutes. Many patients experience transient penile pain and/or local aching after administration and during intercourse, which is caused by the use of the drug alprostadil.

Alprostadil is the first pharmacologic agent used in the transurethral system for erection. Alprostadil is the generic name for the synthetic version of prostaglandin E1, a naturally occurring vasodilator present throughout the body and at high levels in seminal fluid. There are four dosage strengths of alprostadil utilized in MUSE: 125 mcg, 250 mcg, 500 mcg, and 1000 mcg. It is recommended that patients initiating therapy with MUSE be titrated to the lowest effective dose under the supervision of a physician.

The Company's second transurethral product for the treatment of ED, ALIBRA, utilizes a low 125 mcg dose of alprostadil administered in combination with 500 mcg of prazosin hydrochloride. Because alprostadil and prazosin affect vasodilation by complimentary mechanisms, this combination product is designed to provide adequate efficacy and safety with a relatively low dose of alprostadil. Since it is not necessary for patients to titrate among multiple doses, ALIBRA, pending regulatory approval, may provide patients with the advantage of initiating therapy at home, as opposed to dose titration in the physician's office.

#### ADVANTAGES OF TRANSURETHRAL THERAPY

The Company's transurethral system for erection is designed to overcome the limitations of other available therapies through its unique product attributes that include:

**Safety.** The Company's transurethral system for erection is a safe local treatment for patients. Because therapeutic levels of drug are delivered locally to the erectile tissues with minimal systemic drug exposure, the opportunity for systemic drug-drug and drug-disease interactions is minimized. Transurethral therapy, therefore, offers an alternative to oral treatments that are delivered to the erectile tissues via the systemic circulation and may be more susceptible to these types of interactions.

**Ease of Administration.** The Company's transurethral system for erection is easy to use with minimal instruction, unlike needle injection therapy that requires precise injection into the penis.

**Minimally-invasive.** The Company's transurethral system for erection utilizes urethral delivery, permitting topical application to the urethral lining.

**Discreet.** The Company's transurethral system for erection utilizes a small, single-use disposable applicator that can be discreetly applied and is easily integrated into the normal sexual life of the patient. Administration takes less than a minute.

Quality of Erection. The Company's transurethral system for erection therapy mimics the normal vasoactive process, producing an erection that is more natural than those resulting from needle injection therapy, vacuum constriction devices or penile implants.

#### CURRENT THERAPIES

In addition to MUSE, the primary physiological therapies currently utilized for the treatment of ED are:

Oral Medications. In 1998, Pfizer Inc. received clearance from the FDA to market its oral treatment for ED, Viagra. Commercial introduction of this new competitive product adversely affected the Company's business, financial condition and results of operations. Currently, sildenafil accounts for over 98% of prescriptions for pharmaceutical products to treat ED. Yohimbine is another oral medication currently prescribed in the U.S. for the treatment of ED. Other large pharmaceutical companies are also actively engaged in the development of therapies for the treatment of ED.

Needle Injection Therapy. This form of treatment involves the needle injection of pharmacologic agents directly into the penis. The only pharmacologic agent that is currently approved for this indication is alprostadil (which is also the active ingredient in MUSE). Alprostadil is also used by many doctors in combination with other vasodilators, most commonly phentolamine and papaverine. Injection therapy requires a prescription from a physician and instruction on self-injection. Side effects may include pain associated with injection, local pain and aching, priapism (persistent prolonged erections), fibrosis (build-up of scar tissue) and bleeding.

Vacuum Constriction Devices. This form of treatment involves the use of a mechanical system that creates a vacuum around the penis, causing the erectile bodies to fill with blood. A constriction band is then placed around the base of the penis to impede blood drainage and maintain the erection. Vacuum constriction devices are large, mechanical devices that can be unwieldy and somewhat difficult to use. In addition, the erection may not seem natural since only the part of the penis beyond the constriction band is rigid, and the penis can become cold and discolored due to the constriction of blood flow. Complications encountered by some users of vacuum constriction devices include pain and difficulty ejaculating.

Penile Implants. This therapy involves the surgical implantation of a semi-rigid, rigid or inflatable device into the penile structure to mechanically simulate an erection. In addition to the risks associated with surgical procedures, there is a significant rate of complication with implants such as infection and mechanical failure of the device. This may necessitate a second surgical procedure to remove or reposition the device. In addition, due to the scarring associated with the implant procedure, the patient may no longer be a viable candidate for less radical therapies.

#### MANUFACTURING

The Company leases 90,000 square feet of space in Lakewood, New Jersey for its manufacturing operation which includes formulation, filling, packaging, analytical laboratories, storage, distribution and administrative offices. The FDA and the Medicines Control Agency ("MCA") authorized the Company to begin commercial production and shipment of MUSE from this facility in June and March 1998, respectively. The Company has met all market demands for the supply of MUSE utilizing its high quality New Jersey manufacturing facility.

#### GOVERNMENT REGULATION

The Company's research, pre-clinical development, clinical trials, manufacturing and marketing of its products are subject to extensive regulation by numerous governmental authorities in the U.S. and other countries. Clinical trials, manufacturing and marketing of the Company's products are and will be subject to the rigorous testing and approval processes of the FDA and equivalent foreign regulatory agencies. The process of obtaining FDA and other required regulatory approvals is lengthy and expensive. In November 1996, the Company received final marketing clearance from the FDA for MUSE. In November 1997, the

Company obtained regulatory marketing clearance by the MCA to market MUSE in the United Kingdom. MUSE has also been approved in more than 40 countries around the globe.

After regulatory approval is obtained, the Company's products are subject to continual review. The Company submitted marketing applications for its second-generation product, ALIBRA, to the FDA in December 1999 and with the EMEA in May 2000. In October 2000, the Company withdrew its application from the FDA. VIVUS has met with both the FDA and the EMEA to determine what additional data is required to obtain marketing clearance for ALIBRA. There can be no assurance, however, that the Company will be successful in obtaining approvals for ALIBRA.

#### EMPLOYEES

As of March 9, 2001, the Company employed 133 persons. Of these employees, 97 are located at the manufacturing facility in Lakewood, New Jersey; and 36 are located at the Company's corporate headquarters in Mountain View, CA and other U.S. and international locations. None of the Company's current employees are represented by a labor union or are the subject of a collective bargaining agreement. The Company believes that it maintains good relations with its employees.

This Form 10-K contains "forward-looking" statements about future financial results, future products and other events that have not yet occurred. For example, statements like we "expect," we "anticipate" or we "believe" are forward-looking statements. Investors should be aware that actual results may differ materially from our expressed expectations because of risks and uncertainties about the future. We will not necessarily update the information in this Form 10-K if any forward-looking statement later turns out to be inaccurate. Details about risks affecting various aspects of our business are discussed throughout this Form 10-K. Investors should read all of these risks carefully, and should pay particular attention to risks affecting the following areas: new product development and uncertainty of product approvals (pages 10 and 11); intense competition (page 11); future capital needs and uncertainty of additional financing (pages 11 and 12); limited sales and marketing in the U.S. (page 12); dependence on third parties (pages 12 and 13); raw materials (page 13); single manufacturing facility (page 13); and other risk factors as stated (pages 10 through 18).

## RISK FACTORS

### NEW PRODUCT DEVELOPMENT AND UNCERTAINTY OF PRODUCT APPROVALS

The Company's future operating results may be adversely affected if the Company is unable to continue to develop, manufacture and bring to market new drug products rapidly. The process of developing new drugs and/or therapeutic products is inherently complex and uncertain. The Company must make long-term investments and commit significant resources before knowing whether its development programs will eventually result in products that will receive regulatory approval and achieve market acceptance. After the FDA and international regulatory authorities approve a product, the Company must manufacture sufficient volumes to meet market demand. This is a process that requires accurate forecasting of market demand. Given existing treatments and the number of products introduced in the market each year, the drug development process becomes increasingly difficult, expensive and risky. There is no guarantee that future clinical studies will confirm the safety and efficacy of any product in development or that the Company will receive regulatory approval for such products. Further, even if the Company were to receive regulatory approval for a product, there can be no assurance that such product would prove to be commercially successful.

In January 2001, VIVUS signed a licensing agreement with TANABE SEIYAKU ("TANABE"), a leading Japanese pharmaceutical company, for TANABE's proprietary phosphodiesterase type 5 (PDE5) inhibitor compound TA-1790 for the oral and local treatment of male and female sexual dysfunction. TANABE has conducted a Phase I clinical trial and VIVUS intends to initiate additional clinical studies required for regulatory approval of an oral treatment for ED. However, as with any pharmaceutical under development, there are significant risks in development, regulatory approval and commercialization of new compounds. There are no guarantees that future clinical studies will confirm the preliminary results from the Phase I clinical trial or that the compound TA-1790 will receive regulatory approval for any indication. Further, even if the Company were to receive regulatory approval for a product, there can be no assurance that such a product would prove to be commercially successful or profitable.

In September 2000, the Company submitted an IND to the FDA to begin clinical studies with its FSD product, ALISTA. Clinical studies will be focused on the treatment of FSAD, a subcategory of FSD. In January 2001, the Company began enrollment of patients in a Phase II multi-center study to evaluate the safety and efficacy of ALISTA. There can be no assurances that the clinical studies will be successful. Even if the trials are successful, and the Company eventually files an NDA for ALISTA with the FDA, there are no assurances that it would be approved. Even if ALISTA eventually becomes an approved product, there can be no assurances that this treatment for FSD will be successful in the marketplace. Furthermore, the FDA could suspend clinical studies at any time if it is believed that the subjects participating in such studies are being exposed to unacceptable health risks.

In a proof of concept study completed during the first half of 2000, the effect of on-demand therapy with several classes of compounds for the treatment of premature ejaculation (PE) was evaluated. This study demonstrated statistically significant effects on ejaculatory latency, and additional formulation work to

optimize the drug product for this indication is ongoing. The Company anticipates resuming clinical studies once this formulation work has been completed. There is no guarantee that the Company will be able to optimize this formulation. Further, even if the formulation is optimized, there can be no assurance that future clinical studies will confirm the preliminary results in the proof of concept study or that a product for the treatment of PE would prove to be commercially successful.

In May 2000, the Company filed for marketing authorization for ALIBRA with the European Agency for the Evaluation of Medicinal Products (EMA) under the Centralized Process in Europe. The Company met with the EMA and continues to discuss its pending European application. Based on these discussions, the EMA may (1) require the Company to provide more data; (2) require the Company to perform additional clinical trials; or (3) not grant approval of the application. Even if ALIBRA is approved, there can be no assurances that this transurethral system to treat ED will be successful in the marketplace.

In December 1999, the Company submitted an NDA to the FDA to market ALIBRA, which it subsequently withdrew in October 2000. The Company met with the FDA in December 2000 and continues to communicate with the FDA to determine what additional data is required to obtain marketing clearance for ALIBRA. There can be no assurance that the Company will re-file an NDA for ALIBRA. Even if the Company does re-file an NDA for ALIBRA, there can be no assurance that it will be approved or that it will be successful in the marketplace.

#### INTENSE COMPETITION

Competition in the pharmaceutical and medical products industries is intense and is characterized by extensive research efforts and rapid technological progress. Certain treatments for ED exist, such as oral medications, needle injection therapy, vacuum constriction devices and penile implants, and the manufacturers of these products will continue to improve these therapies. The most significant competitive therapy is Viagra, an oral medication marketed by Pfizer, which received regulatory approvals in the U.S. in March 1998 and in the European Union in September 1998. The commercial launch of Viagra in the U.S. in April 1998 significantly decreased demand for MUSE.

Additional competitive products in the ED market include needle injection therapy products from Pharmacia Upjohn and Schwartz Pharma, which were approved by the FDA in July 1995 and June 1997, respectively. Other large pharmaceutical companies are also actively engaged in the development of therapies for the treatment of ED. These companies have substantially greater research and development capabilities as well as substantially greater marketing, financial and human resources abilities than VIVUS. In addition, many of these companies have significantly greater experience than the Company in undertaking pre-clinical testing, human clinical trials and other regulatory approval procedures. For instance, ICOS Corporation and Bayer AG both have oral medications in late stage clinical testing for ED; and Senetek has a needle injection therapy product approved recently in Denmark and has filed for approval in other countries. These entities may market commercial products either on their own or through collaborative efforts. For example, ICOS Corporation formed a joint venture with Eli Lilly in October 1998 to jointly develop and market its oral treatment. The Company's competitors may develop technologies and products that are more effective than those currently marketed or being developed by the Company. Such developments would render the Company's products less competitive or possibly obsolete. The Company is also competing with respect to marketing capabilities and manufacturing efficiency, areas in which it has limited experience.

#### FUTURE CAPITAL NEEDS AND UNCERTAINTY OF ADDITIONAL FINANCING

The Company anticipates that its existing capital resources combined with anticipated future cash flows will be sufficient to support the Company's operating needs throughout 2001. However, the Company anticipates that it will be required to obtain additional financing to fund the development of its R&D pipeline in future periods in addition to the possible launch of any future products. There can be no assurance that the Company will be able to obtain such financing when required, on acceptable terms or at all.

The Company expects to evaluate potential financing sources, including, but not limited to, the issuance of additional equity or debt securities, corporate alliances, joint ventures, and licensing agreements to fund the

development and possible commercial launch of its future products. The sale of additional equity securities would result in additional dilution to the Company's stockholders. The Company's working capital and additional funding requirements will depend upon numerous factors, including: (i) the progress of the Company's R&D programs; (ii) the timing and results of pre-clinical testing and clinical trials; (iii) results of operations; (iv) demand for MUSE; (v) technological advances; (vi) the level of resources that the Company devotes to sales and marketing capabilities; and (vii) the activities of competitors.

#### LIMITED SALES AND MARKETING IN THE U.S.

The Company supports MUSE sales in the U.S. through physician and patient information/help lines, a small targeted sales support group for major accounts, product education newsletters, and participation in national urologic and sexual dysfunction forums and conferences, such as the American Urological Association annual and regional meetings and the International Society for Impotence Research. There can be no assurance that demand for the Company's product MUSE will continue or that the Company will be able to adequately support sales of MUSE in the U.S.

#### DEPENDENCE ON THIRD PARTIES

In November 2000, the Company entered into an agreement granting Paladin exclusive marketing and distribution rights for MUSE in Canada. This agreement does not have minimum purchase commitments and the Company is entirely dependent on Paladin's efforts to distribute and sell the Company's product effectively in Canada. There can be no assurance that such efforts will be successful or that Paladin will continue to support the product.

In June 2000, the Company entered into an agreement granting Abbott exclusive marketing and distribution rights for MUSE in all countries outside the U.S. and Canada. This agreement does not have minimum purchase commitments and the Company is entirely dependent on Abbott's efforts to distribute and sell the Company's product effectively in all markets except the U.S. and Canada. There can be no assurance that such efforts will be successful or that Abbott will continue to support the product.

In 1996, the Company entered into a distribution agreement with CORD Logistics, Inc. ("CORD"), a wholly owned subsidiary of Cardinal Health, Inc. Under this agreement, CORD (i) warehouses the Company's finished goods for U.S. distribution, (ii) takes customer orders, (iii) picks, packs and ships its product, (iv) invoices customers, and (v) collects related receivables. As a result of this distribution agreement with CORD, the Company is heavily dependent on CORD's efforts to fulfill orders and warehouse its products effectively in the U.S. There can be no assurance that such efforts will be successful.

In 1996, the Company entered into an agreement with Gibraltar Laboratories (Gibraltar). Under this agreement, Gibraltar performs sterility testing on finished product manufactured by the Company to assure that they comply with product specifications. Gibraltar also performs microbial testing on water and compressed gases used in the manufacturing process and microbial testing on environmental samples to assure that the manufacturing environment meets appropriate cleanliness standards. As a result of this testing agreement, the company is dependent on Gibraltar to perform testing and issue reports on finished product and the manufacturing environment in a manner that meets regulatory compliance standards. There can be no assurance that such effort will be successful.

In 1996, the Company entered into an agreement with WRB Communications ("WRB") to handle patient and healthcare professional hotlines for the Company. WRB maintains a staff of healthcare professionals to handle questions and inquiries about MUSE and ACTIS. These calls may include complaints about the Company's product due to efficacy or quality, as well as the reporting of adverse events. As a result of this agreement, the Company is dependent on WRB to effectively handle these calls and inquiries. There can be no assurance that such effort will be successful.

In 1996, the Company entered into a distribution agreement with Integrated Commercialization Services ("ICS"), a subsidiary of Bergen Brunswig Corporation. ICS provides "direct-to-physician" distribution capabilities in support of U.S. marketing and sales efforts. As a result of this distribution agreement with ICS,

the Company is dependent on ICS's efforts to distribute product samples effectively. There can be no assurance that such efforts will be successful.

#### RAW MATERIALS

The Company has obtained its current supply of alprostadil from two approved sources. The first is Spolana Chemical Works a.s. in Neratovice, Czech Republic ("Spolana"). The second is CHINOIN Pharmaceutical and Chemical Works Co., Ltd. ("Chinois"). Chinois is the Hungarian subsidiary of the French pharmaceutical company Sanofi Winthrop. The Company is required to receive regulatory approval for suppliers. At the present time, Spolana is the sole source of supply for alprostadil used in the manufacture of product for distribution in Europe, and the Company has a limited supply. Certain restrictions have been put in place by the European regulatory authorities that would require a variation to be approved before VIVUS can use the Chinois alprostadil supply for European manufacture. The Company is in the process of transferring licenses in Europe to Abbott. Abbott intends to file variations with the European regulatory authorities for the use of Chinois alprostadil. There can be no assurance that such variations will be approved in a timely manner or at all, which could have a material impact on the Company's ability to supply MUSE to Abbott for distribution in Europe.

Furthermore, alprostadil is subject to periodic re-testing to assure it continues to meet specifications. There can be no guarantees the material will pass these testing procedures and continue to be usable material. There is a long lead time for manufacturing alprostadil. A short supply of alprostadil to be used in the manufacture of MUSE would have a material adverse effect on the Company's business, financial condition and results of operations.

#### SINGLE MANUFACTURING FACILITY

The Company leases 90,000 square feet of space in Lakewood, New Jersey, in which it constructed manufacturing, warehousing and testing facilities. The FDA and MCA authorized the Company to begin commercial production and shipment of MUSE from this facility in June and March 1998, respectively. The New Jersey facility is currently the only place MUSE is manufactured. The Company has no immediate plans to construct another manufacturing site. Being that MUSE is produced with custom made equipment under specific manufacturing conditions, the inability of the New Jersey manufacturing facility to produce MUSE for whatever reason could have a material adverse effect on the Company's business, financial condition and results of operations.

#### RISKS RELATING TO INTERNATIONAL OPERATIONS

The Company's product MUSE is currently marketed internationally. Changes in overseas economic and political conditions, currency exchange rates, foreign tax laws or tariffs or other trade regulations could have a material adverse effect on the Company's business, financial condition and results of operations. The international nature of the Company's business is also expected to subject it and its representatives, agents and distributors to laws and regulations of the foreign jurisdictions in which they operate or where the Company's product is sold. The regulation of drug therapies in a number of such jurisdictions, particularly in the European Union, continues to develop, and there can be no assurance that new laws or regulations will not have a material adverse effect on the Company's business, financial condition and results of operations. In addition, the laws of certain foreign countries do not protect the Company's intellectual property rights to the same extent as do the laws of the U.S.

#### HISTORY OF LOSSES

The Company has generated a cumulative net loss of \$83.3 million for the period from its inception through December 31, 2000. The Company must successfully manufacture and market MUSE and keep its expenditures in line with lower product revenues. The Company is subject to a number of risks including its ability to market, distribute and sell its product in the U.S., its reliance on Abbott to market and distribute MUSE internationally, its reliance on Paladin to market and distribute MUSE in Canada, intense competi-

tion, and its reliance on a single therapeutic approach to ED. There can be no assurance that the Company will be able to achieve profitability on a sustained basis. Accordingly, there can be no assurance of the Company's future success.

#### DEPENDENCE ON THE COMPANY'S TRANSURETHRAL SYSTEM FOR ERECTION

MUSE, a drug product developed by the Company to treat ED, relies on a single therapeutic approach, a transurethral system for erection. The existence of side effects or dissatisfaction with this product may impact a patient's decision to use or continue to use or a physician's decision to recommend this therapeutic approach as a therapy for the treatment of ED, thereby affecting the commercial viability of MUSE. In addition, technological changes or medical advancements could diminish or eliminate the commercial viability of the Company's products, the results of which could have a material effect on the business operations and results of the Company.

#### PATENTS AND PROPRIETARY RIGHTS

The Company's policy is to aggressively maintain its patent position and to enforce all of its intellectual property rights.

The Company is the exclusive licensee of U.S. and Canadian patents originally filed in the name of Dr. Gene Voss. These patents claim methods of treating ED with a vasodilator-containing ointment that is administered either topically or transurethraly.

The Company is also the exclusive licensee of patents and patent applications filed in the name of Dr. Nils G. Kock, in numerous countries. Four U.S. patents have issued directed to methods and compositions for treating ED by transurethraly administering an active agent. Patents have also been granted in Australia, Austria, Belgium, Canada, Finland, France, Germany, Great Britain, Greece, Ireland, Italy, Japan, Luxembourg, the Netherlands, New Zealand, Norway, Spain, Sweden and South Africa. Patent applications are pending in Denmark and Romania. The foreign patents and applications, like the U.S. patents, are directed to the treatment of ED by transurethral administration of certain active substances including alpha-receptor blockers, vasoactive polypeptides, prostaglandins or nitroglycerin dispersed in a hydrophilic vehicle.

The Company is the sole assignee of five U.S. patents deriving from patent applications originally filed by Alza, covering inventions Dr. Virgil Place made while he was an employee of Alza. The patents are directed to dosage forms for administering a therapeutic agent to the urethra, methods for treating ED, and specific drug formulations that can be delivered transurethraly for the treatment of ED. With one exception, the patents derive from patent applications that were filed in the U.S. prior to June 8, 1995, and will therefore have a seventeen-year patent term calculated from the date of patent grant. Foreign patents have been granted in Australia, Europe (including Austria, Belgium, Denmark, France, Germany, Great Britain, Greece, Italy, Luxembourg, the Netherlands, Spain, Sweden and Switzerland), Finland, Ireland, Mexico, New Zealand, Norway, Portugal, South Africa and South Korea, and foreign applications are pending in Canada and Japan.

The Company's license and assignment agreements for these patents and patent applications are royalty-bearing and do not expire until the licensed patents expire. These license and assignment agreements provide that the Company may assume responsibility for the maintenance and prosecution of the patents and bring infringement actions.

In addition to the Voss, Kock and Place patents and applications identified above, the Company has thirteen issued U.S. patents, twelve pending U.S. patent applications, three granted foreign patent, and twenty-two pending foreign patent applications. Several of these patents and applications further address the prevention, treatment and diagnosis of ED, while others are directed to prevention and/or treatment of other types of sexual dysfunction, including PE and FSD. One of the Company's issued patents covers the Company's ACTIS venous flow control device.

The Company has entered into an agreement with AndroSolutions, Inc., a privately held biomedical corporation based in Knoxville, Tennessee, that owns patents and applications complementary to the Company's patents and applications directed to the treatment of FSD. Both the Company and AndroSolutions

have contributed their FSD patents and applications into a jointly formed Limited Liability Company, ASIVI, LLC, which exclusively licenses to VIVUS worldwide rights to the common patents and applications.

The Company's success will depend in large part on the strength of its current and future patent position for the treatment of ED, PE and FSD. The Company's patent position, like that of other pharmaceutical companies, is highly uncertain and involves complex legal and factual questions. The claims of a U.S. or foreign patent application may be denied or significantly narrowed, and patents that ultimately issue may not provide significant commercial protection to the Company. The Company could incur substantial costs in proceedings before the U.S. Patent and Trademark Office, including interference proceedings. These proceedings could also result in adverse decisions as to the priority of the Company's licensed or assigned inventions. There is no assurance that the Company's patents will not be successfully challenged or designed around by others.

The Company is presently involved in an opposition proceeding that was instigated by the Pharmedic Company against a European patent, inventors Nils G. Kock et al., that is exclusively licensed to VIVUS. As a result of the opposition proceeding, certain pharmaceutical composition claims in the European patent were held unpatentable by the Opposition Division of the EPO. The patentability of all other claims in the patent was confirmed, i.e., those claims directed to the use of active agents in the treatment of ED, and to a pharmaceutical composition claim for prazosin. The Company appealed the EPO's decision with respect to the pharmaceutical composition claims that were held unpatentable. The Pharmedic Company appealed the EPO's decision with respect to the claims that were held patentable, but has since withdrawn the appeal. Despite the withdrawal of the Pharmedic Company from the appeal process, the Company has continued with its own appeal in an attempt to reinstate the composition claims. The EPO Appeals Board must make its own finding whether the claims that were deemed unpatentable by the Opposition Division are indeed patentable before it can reverse the Opposition Division's decision. There can be no assurance that the appeal will be successful or that further challenges to the Company's European patent will not occur should the Company try to enforce the patent in the various European courts.

The Company was also the first to file a Notice of Opposition to Pfizer's European patent application claiming the use of phosphodiesterase inhibitors to treat ED. Numerous other companies have also opposed the patent, and the Company will support these other entities in their oppositions as necessary.

There can be no assurance that the Company's products do not or will not infringe on the patent or proprietary rights of others. The Company may be required to obtain additional licenses to the patents, patent applications or other proprietary rights of others. There can be no assurance that any such licenses would be made available on terms acceptable to the Company, if at all. If the Company does not obtain such licenses, it could encounter delays in product introductions while it attempts to design around such patents, or the development, manufacture or sale of products requiring such licenses could be precluded. The Company believes there will continue to be significant litigation in the pharmaceutical industry regarding patent and other intellectual property rights.

In addition to its patent portfolio, the Company also relies on trade secrets and other unpatented proprietary technology. No assurance can be given that the Company can meaningfully protect its rights in such unpatented proprietary technology or that others will not independently develop substantially equivalent proprietary products and processes or otherwise gain access to the Company's proprietary technology. The Company seeks to protect its trade secrets and proprietary know-how, in part, through confidentiality agreements with employees and consultants. There can be no assurance that the agreements will not be breached, that the Company will have adequate remedies for any breach, or that the Company's trade secrets will not otherwise become known or be independently developed by competitors. In addition, protracted and costly litigation may be necessary to enforce and determine the scope and validity of the Company's proprietary rights.

#### DEPENDENCE ON SINGLE SOURCE OF SUPPLY

The Company relies on a single injection molding company, The Kipp Group ("Kipp"), for its supply of plastic applicator components. In turn, Kipp obtains its supply of resin, a key ingredient of the applicator, from

a single source, Huntsman Corporation. The Company also relies on a single source, E-Beam Services, Inc. ("E-Beam"), for sterilization of its product. There can be no assurance that the Company will be able to identify and qualify additional sources of plastic components or an additional sterilization facility. The Company is required to receive FDA approval for suppliers. The FDA may require additional clinical trials or other studies prior to accepting a new supplier. Until the Company secures and qualifies additional sources of plastic components or an additional sterilization facility, it is entirely dependent upon Kipp and E-Beam. If interruptions in these supplies or services were to occur for any reason, including a decision by Kipp and/or E-Beam to discontinue manufacturing or services, political unrest, labor disputes or a failure of Kipp and/or E-Beam to follow regulatory guidelines, the development and commercial marketing of MUSE and other potential products could be delayed or prevented. An extended interruption in sterilization services or the Company's supply of plastic components would have a material adverse effect on the Company's business, financial condition and results of operations.

#### DEPENDENCE ON KEY PERSONNEL

The Company's success is highly dependent upon the skills of a limited number of key management personnel. To reach its business objectives, the Company will need to retain and hire qualified personnel in the areas of manufacturing, research and development, clinical trial management and pre-clinical testing. There can be no assurance that the Company will be able to hire or retain such personnel as the Company must compete with other companies, academic institutions, government entities and other agencies. The loss of any of the Company's key personnel or the failure to attract or retain necessary new employees could have an adverse effect on the Company's research, product development and business operations.

#### GOVERNMENT REGULATION

The Company's research, preclinical development, clinical studies, manufacturing and marketing of its products are subject to rigorous testing and extensive regulation processes of the FDA and equivalent foreign regulatory agencies. To date, the Company's product MUSE has received marketing clearance in more than 40 countries worldwide.

After regulatory approval is obtained, the Company's products are subject to continual review. Manufacturing, labeling and promotional activities are continually regulated by the FDA and equivalent foreign regulatory agencies, and the Company must also report certain adverse events involving its drugs to these agencies. Previously unidentified adverse events or an increased frequency of adverse events that occur post-approval could result in labeling modifications of approved products, which could adversely affect future marketing. Finally, approvals may be withdrawn if compliance with regulatory standards is not maintained or if problems occur following initial marketing. The restriction, suspension or revocation of regulatory approvals or any other failure to comply with regulatory requirements would have a material adverse effect on the Company's business, financial condition and results of operations.

Failure to comply with the applicable regulatory requirements can result in fines, suspensions of regulatory approvals, product recalls, operating restrictions and criminal prosecution, among other outcomes. In addition, the marketing and manufacturing of pharmaceutical products are subject to continuing FDA and other regulatory review, and later discovery of previously unknown problems with a product, manufacturer or facility may result in the FDA and other regulatory agencies requiring further clinical research or restrictions on the product or the manufacturer, including withdrawal of the product from the market. The restriction, suspension or revocation of regulatory approvals or any other failure to comply with regulatory requirements would have a material adverse effect on the Company's business, financial condition and results of operations.

Failure to maintain satisfactory compliance with Current Good Manufacturing Practices ("cGMP") would have a material adverse effect on the Company's ability to continue to market and distribute its products and, in the most serious cases, could result in the issuance of additional Warning Letters, seizure or recall of products, civil fines or closure of the Company's manufacturing facility until such cGMP compliance is achieved.

The Company obtains the necessary raw materials and components for the manufacture of MUSE as well as certain services, such as testing and sterilization, from third parties. The Company currently contracts with suppliers and service providers, including foreign manufacturers that are required to comply with strict standards established by the Company. Certain suppliers and service providers are required by the Federal Food, Drug, and Cosmetic Act, as amended, and by FDA regulations to follow cGMP requirements and are subject to routine periodic inspections by the FDA and by certain state and foreign regulatory agencies for compliance with cGMP requirements and other applicable regulations. Certain of the Company's suppliers were inspected for cGMP compliance as part of the approval process. However, upon routine re-inspection of these facilities, there can be no assurance that the FDA and other regulatory agencies will find the manufacturing process or facilities to be in compliance with cGMP requirements and other regulations.

Failure to achieve satisfactory cGMP compliance as confirmed by routine inspections could have a material adverse effect on the Company's ability to continue to manufacture and distribute its products and, in the most serious case, result in the issuance of a regulatory warning letter or seizure or recall of products, injunction and/or civil fines or closure of the Company's manufacturing facility until cGMP compliance is achieved.

#### UNCERTAINTY OF PHARMACEUTICAL PRICING AND REIMBURSEMENT

In the U.S. and elsewhere, sales of pharmaceutical products are dependent, in part, on the availability of reimbursement to the consumer from third party payors, such as government and private insurance plans. Third party payors are increasingly challenging the prices charged for medical products and services. With the introduction of Viagra, third party payors have begun to restrict or eliminate reimbursement for ED treatments. While a large percentage of prescriptions in the U.S. for MUSE have been reimbursed by third party payors since its commercial launch in January 1997, there can be no assurance that the Company's products will be considered cost effective and that reimbursement to the consumer will continue to be available or sufficient to allow the Company to sell its products on a competitive basis.

In addition, certain healthcare providers are moving towards a managed care system in which such providers contract to provide comprehensive healthcare services, including prescription drugs, for a fixed cost per person. The Company hopes to further qualify MUSE for reimbursement in the managed care environment. However, the Company is unable to predict the reimbursement policies employed by third party healthcare payors. Furthermore, reimbursement for MUSE could be adversely affected by changes in reimbursement policies of governmental or private healthcare payors.

#### PRODUCT LIABILITY AND AVAILABILITY OF INSURANCE

The commercial launch of MUSE exposes the Company to a significant risk of product liability claims due to its availability to a large population of patients. In addition, pharmaceutical products are subject to heightened risk for product liability claims due to inherent side effects. The Company details potential side effects in the patient package insert and the physician package insert, both of which are distributed with MUSE, and the Company maintains product liability insurance coverage. However, the Company's product liability coverage is limited and may not be adequate to cover potential product liability exposure. Product liability insurance is expensive, difficult to maintain, and current or increased coverage may not be available on acceptable terms, if at all. Product liability claims brought against the Company in excess of its insurance coverage, if any, could have a material adverse effect upon the Company's business, financial condition and results of operations.

#### UNCERTAINTY AND POSSIBLE NEGATIVE EFFECTS OF HEALTHCARE REFORM

The healthcare industry is undergoing fundamental changes that are the result of political, economic and regulatory influences. The levels of revenue and profitability of pharmaceutical companies may be affected by the continuing efforts of governmental and third party payors to contain or reduce healthcare costs through various means. Reforms that have been and may be considered include mandated basic healthcare benefits, controls on healthcare spending through limitations on the increase in private health insurance premiums and

Medicare and Medicaid spending, the creation of large insurance purchasing groups and fundamental changes to the healthcare delivery system. Due to uncertainties regarding the outcome of healthcare reform initiatives and their enactment and implementation, the Company cannot predict which, if any, of the reform proposals will be adopted or the effect such adoption may have on the Company. There can be no assurance that future healthcare legislation or other changes in the administration or interpretation of government healthcare or third party reimbursement programs will not have a material adverse effect on the Company. Healthcare reform is also under consideration in some other countries.

#### POTENTIAL VOLATILITY OF STOCK PRICE

The stock market has experienced significant price and volume fluctuations unrelated to the operating performance of particular companies. In addition, the market price of the Company's common stock has been highly volatile and is likely to continue to be so. Factors such as the Company's ability to increase demand for its product in the U.S., the Company's ability to successfully sell its product in the U.S. and internationally, variations in the Company's financial results and its ability to obtain needed financing, announcements of technological innovations or new products by the Company or its competition, comments by security analysts, adverse regulatory actions or decisions, any loss of key management, the results of the Company's clinical trials or those of its competition, changing governmental regulations, patents or other proprietary rights, product or patent litigation or public concern as to the safety of products developed by the Company may have a significant effect on the market price of the Company's common stock.

#### ANTI-TAKEOVER EFFECT OF PREFERRED SHARES RIGHTS PLAN AND CERTAIN CHARTER AND BYLAW PROVISIONS

In February 1996, the Company's Board of Directors authorized its reincorporation in the State of Delaware (the "Reincorporation") and adopted a Preferred Shares Rights Plan. The Company's Reincorporation into the State of Delaware was approved by its stockholders and became effective in May 1996. The Preferred Shares Rights Plan provides for a dividend distribution of one Preferred Shares Purchase Right (a "Right") on each outstanding share of the Company's common stock. The Rights will become exercisable following the tenth day after a person or group announces acquisition of 20 percent or more of the Company's common stock, or announces commencement of a tender offer, the consummation of which would result in ownership by the person or group of 20 percent or more of the Company's common stock. The Company will be entitled to redeem the Rights at \$0.01 per Right at any time on or before the tenth day following acquisition by a person or group of 20 percent or more of the Company's common stock.

The Preferred Shares Rights Plan and certain provisions of the Company's Certificate of Incorporation and Bylaws may have the effect of making it more difficult for a third party to acquire, or of discouraging a third party from attempting to acquire, control of the Company. The Company's Certificate of Incorporation allows the Company to issue preferred stock without any vote or further action by the stockholders, and certain provisions of the Company's Certificate of Incorporation and Bylaws eliminate the right of stockholders to act by written consent without a meeting, specify procedures for director nominations by stockholders and submission of other proposals for consideration at stockholder meetings, and eliminate cumulative voting in the election of directors. Certain provisions of Delaware law could also delay or make more difficult a merger, tender offer or proxy contest involving the Company, including Section 203, which prohibits a Delaware corporation from engaging in any business combination with any interested stockholder for a period of three years unless certain conditions are met. The Preferred Shares Rights Plan, the possible issuance of preferred stock, the procedures required for director nominations and stockholder proposals and Delaware law could have the effect of delaying, deferring or preventing a change in control of the Company, including without limitation, discouraging a proxy contest or making more difficult the acquisition of a substantial block of the Company's common stock. These provisions could also limit the price that investors might be willing to pay in the future for shares of the Company's common stock.

## ITEM 2. PROPERTIES

The Company leases 90,000 square feet of space in New Jersey in which it has constructed manufacturing and testing facilities. The FDA and MCA authorized the Company to begin commercial production and shipment of MUSE from this facility in June and March 1998, respectively.

In January 2000, the Company leased 14,237 square feet of space in Mountain View, California, which serves as the principal site for administration, clinical trial management, regulatory affairs and monitoring of product production and quality control, as well as its research and development activities.

## ITEM 3. LEGAL PROCEEDINGS

On September 11, 2000, the Company filed a Notice and Demand for Arbitration with the American Arbitration Association ("AAA") against AndroSolutions, Inc. ("ASI") in connection with certain contractual provisions governing the parties' joint venture, ASIVI, LLC ("ASIVI"). The Company seeks an award declaring that it is not liable to ASI for a \$625,000 milestone payment that ASI claims is due under the parties' Memorandum of Understanding dated October 14, 1999 (the "MOU"). The Company also seeks an award directing ASI's specific performance of other non-monetary contractual obligations. On October 5, 2000, ASI responded to the arbitration demand, denying all claims and asserting its entitlement to the \$625,000 milestone payment. ASI also asserted counterclaims seeking an award directing VIVUS' specific performance of other non-monetary contractual obligations. The Company believes ASI's counterclaims are without merit and, on October 16, 2000, it filed its response to the counterclaims, denying all liability. The parties began an arbitration hearing in December 2000 that was postponed while the parties are attempting to agree on a settlement of the claims. If the parties are not able to reach a settlement, the hearing is expected to be continued in the second quarter of 2001.

On August 23, 2000, VIVUS, Inc. (the "Company") received a notice of Demand for Arbitration from Alza Corporation ("Alza") alleging a breach of a sales force transition agreement dated July 6, 1998. The sales force transition agreement provided for the transition of VIVUS' sales force to Alza, where they would promote both VIVUS' and Alza's products for a period of time. The agreement further provided that VIVUS is to indemnify Alza for claims brought by any member of the sales force relating to such person's employment (or termination) by VIVUS, and that Alza is to indemnify VIVUS for claims brought by any member of the sales force relating to such person's employment (or termination) by Alza. Alza alleges that it is entitled to indemnification from the Company for Alza's attorneys' fees and amounts paid to settle claims relating to Alza's failure to hire a former Company employee. Alza seeks approximately \$507,500 in damages. The Company filed an answer with the AAA on September 22, 2000, in which it denied all of the material allegations of the Demand for Arbitration. The Company is currently engaged in discovery. A briefing schedule has been set with all arbitration briefs to be submitted no later than May 3, 2001. No date has yet been set for an arbitration hearing. The Company believes it has meritorious defenses and it intends to vigorously defend the matter. Nevertheless, an adverse judgment in this litigation is not expected to have a material impact on the Company's financial position.

On May 19, 2000, the Company was named, along with other defendants, in a civil action filed in the Superior Court of New Jersey. The Complaint in this action alleges that plaintiff was the victim of sexual harassment during the second quarter of 1998, while she was working as a temporary worker for the Company at a facility operated by PACO Pharmaceutical Services, Inc. At the time, the Company was leasing space and workers from PACO to assist it with the manufacture of the Company's product, MUSE. The complaint alleges hostile work environment and quid pro quo sexual harassment, and seeks compensatory and punitive damages. The Company denies liability, and intends to defend the case vigorously. At this early stage in the litigation, it is not possible to predict the outcome of the suit with any degree of certainty. In addition, plaintiff has not yet provided the Company with information concerning the extent of her alleged damages, so it is not possible to estimate the extent of any loss in the event plaintiff prevails against the Company. Nevertheless, an adverse judgment in this litigation is not expected to have a material impact on the Company's financial position.

On November 3, 1999, the Company filed a demand for arbitration against Janssen Pharmaceutica International ("Janssen") with the AAA pursuant to the terms of the Distribution Agreement entered into on January 22, 1997. The Company seeks compensation for inventory manufactured in 1998 in reliance on contractual forecasts and orders submitted by Janssen. The Company also seeks compensation for forecasts and order shortfalls attributed to Janssen in 1998, pursuant to the terms of the Distribution Agreement. The Company amended its arbitration demand in August 2000 to include claims for lost profits due to Janssen's failure to use the requisite diligence and reasonable efforts to gain regulatory approval for and launch MUSE in each country of the Territory. This amendment also includes claims based on Janssen's development of a competing product intended for use in the treatment of male ED, in violation of the Distribution Agreement. The Company's amended demand seeks an award of \$7.9 million plus costs and interest. On October 20, 2000, Janssen submitted its response to the Company's amended arbitration demand denying liability on all claims, and asserting counterclaims against the Company for \$1.8 million based on the Company's alleged improper calculation of its Cost of Goods charged to Janssen pursuant to the Distribution Agreement. On November 20, 2000 the Company filed its response to the counterclaims, denying all liability. The Company believes that Janssen's counterclaims are without merit and intends to defend against them vigorously. Administration of the arbitration has been transferred to JAMS and a three-member arbitration panel has been selected. The parties are currently in the process of conducting discovery and anticipate a hearing sometime in the second half of 2001.

In the normal course of business, the Company receives and makes inquiries regarding patent infringement and other legal matters. The Company believes that it has meritorious claims and defenses and intends to pursue any such matters vigorously. The Company is not aware of any asserted or unasserted claims against it where the resolution would have an adverse material impact on the operations or financial position of the Company.

#### ITEM 4. SUBMISSION OF MATTERS TO A VOTE OF SECURITY HOLDERS

No matters were submitted to a vote of the Company's stockholders during the quarter ended December 31, 2000.

## PART II

## ITEM 5. MARKET FOR REGISTRANT'S COMMON EQUITY AND RELATED STOCKHOLDER MATTERS

The Company's common stock trades publicly on the Nasdaq National Market System under the symbol "VVUS." The following table sets forth for the periods indicated the quarterly high and low closing sales prices of the Company's common stock as reported on the Nasdaq stock market.

	THREE MONTHS ENDED			
	MARCH 31	JUNE 30	SEPTEMBER 30	DECEMBER 31
2000				
High.....	\$9.56	\$7.94	\$7.41	\$4.22
Low.....	3.88	4.53	4.25	1.88
1999				
High.....	\$4.81	\$5.31	\$4.72	\$5.69
Low.....	2.06	2.63	2.88	2.00

As of March 9, 2001, there were no outstanding shares of preferred stock and 723 shareholders of record of 32,479,640 shares of outstanding common stock. The Company has not paid any dividends since its inception and does not intend to declare or pay any dividends on its common stock in the foreseeable future. Declaration or payment of future dividends, if any, will be at the discretion of the Company's Board of Directors after taking into account various factors, including the Company's financial condition, operating results and current and anticipated cash needs.

## ITEM 6. SELECTED FINANCIAL DATA

This section presents selected historical data of the Company. The financial statements, related notes thereto, and the section entitled "Management's Discussion and Analysis of Financial Condition and Results of Operations" included elsewhere in the Form 10-K should be read carefully. The selected data is not intended to replace the financial statements.

SELECTED FINANCIAL DATA  
(IN THOUSANDS, EXCEPT PER SHARE AND EMPLOYEE DATA)

## SELECTED QUARTERLY FINANCIAL DATA (UNAUDITED)

	QUARTER ENDED,			
	MARCH 31	JUNE 30	SEPTEMBER 30	DECEMBER 31
<b>2000</b>				
Net sales.....	\$ 7,467	\$ 6,747	\$ 4,978	\$ 7,301
Gross profit.....	\$ 4,540	\$ 3,883	\$ 2,036	\$ 7,968
Net income (loss).....	\$ 1,546	\$ 890	\$ 208	\$ 5,047
Net income (loss) per share:				
Basic.....	\$ 0.05	\$ 0.03	\$ 0.01	\$ 0.16
Diluted.....	\$ 0.05	\$ 0.03	\$ 0.01	\$ 0.15
<b>1999</b>				
Net sales.....	\$ 9,754	\$ 5,811	\$ 6,127	\$21,496
Gross profit.....	\$ 6,151	\$ 2,739	\$ 3,287	\$18,642
Net income (loss).....	\$ 3,792	\$ 292	\$ 897	\$13,820
Net income (loss) per share:				
Basic.....	\$ 0.12	\$ 0.01	\$ 0.03	\$ 0.43
Diluted.....	\$ 0.12	\$ 0.01	\$ 0.03	\$ 0.43
<b>1998</b>				
Net sales.....	\$27,522	\$ 15,983	\$ 20,064	\$11,130
Gross profit.....	\$17,040	\$ 5,279	\$ (8,233)	\$ 4,997
Net income (loss).....	\$(2,390)	\$(24,178)	\$(54,725)	\$ 1,040
Net income (loss) per share:				
Basic.....	\$ (0.07)	\$ (0.76)	\$ (1.72)	\$ 0.03
Diluted.....	\$ (0.07)	\$ (0.76)	\$ (1.72)	\$ 0.03

## SELECTED ANNUAL FINANCIAL DATA

	YEAR ENDED DECEMBER 31,				
	2000	1999	1998	1997	1996
<b>Income Statement Data:</b>					
Product revenue -- U.S.....	\$ 22,474	\$ 21,168	\$ 39,041	\$128,320	\$ --
Product revenue -- International.....	5,200	19,996	32,658	1,017	--
Milestone Revenue.....	--	8,000	3,000	9,000	20,000
Other Revenue.....	--	3,142	--	--	--
Returns.....	(1,181)	(9,118)	--	--	--
<b>Total revenue.....</b>	<b>26,493</b>	<b>43,188</b>	<b>74,699</b>	<b>138,337</b>	<b>20,000</b>
<b>Gross profit.....</b>	<b>18,427</b>	<b>30,819</b>	<b>19,083</b>	<b>100,049</b>	<b>20,000</b>
<b>Operating expenses:</b>					
Research and development.....	4,670	7,884	16,178	12,123	28,279
Selling, general and administrative.....	8,655	6,332	40,477	47,931	11,733
Write-downs and other charges.....	(903)	(1,193)	44,653	5,050	--
<b>Total operating expenses.....</b>	<b>12,422</b>	<b>13,023</b>	<b>101,308</b>	<b>65,104</b>	<b>40,012</b>
Income (loss) from operations.....	6,005	17,796	(82,225)	34,945	(20,012)
Interest and other income.....	2,541	1,994	1,972	4,856	3,485
<b>Income (loss) before taxes.....</b>	<b>\$ 8,546</b>	<b>\$ 19,790</b>	<b>\$ (80,253)</b>	<b>\$ 39,801</b>	<b>\$(16,527)</b>
<b>Net income (loss).....</b>	<b>\$ 7,691</b>	<b>\$ 18,801</b>	<b>\$ (80,253)</b>	<b>\$ 36,617</b>	<b>\$(16,527)</b>
Net income (loss) per diluted share.....	\$ 0.23	\$ 0.58	\$ (2.52)	\$ 1.03	\$ (0.55)
Shares used in per share computation.....	33,428	32,507	31,876	35,559	29,833
<b>Balance Sheet Data (at year end):</b>					
Working capital.....	\$ 32,981	\$ 26,616	\$ 10,324	\$ 54,888	\$ 60,388
Total assets.....	\$ 69,174	\$ 68,760	\$ 54,108	\$150,669	\$ 96,532
Accumulated deficit.....	\$(83,298)	\$(90,989)	\$(109,790)	\$(29,537)	\$(66,154)
Stockholders' equity.....	\$ 50,187	\$ 41,496	\$ 21,677	\$123,930	\$ 89,780
<b>Other Financial Data:</b>					
Common shares outstanding.....	32,461	32,211	31,890	33,168	32,454
Number of employees.....	136	125	101	215	95

## ITEM 7. MANAGEMENT'S DISCUSSION AND ANALYSIS OF FINANCIAL CONDITION AND RESULTS OF OPERATIONS

## OVERVIEW

In the Management Discussion and Analysis section of the 10-K we are providing more detailed information about our operating results and changes in financial position over the past three years. This section should be read in conjunction with the Consolidated Financial Statements and related Notes beginning on page 29.

VIVUS, Inc. ("VIVUS" or the "Company") is a pharmaceutical company developing innovative products to improve quality of life disorders in men and women, with a focus on sexual dysfunction. The Company developed and markets in the U.S. MUSE(R) (alprostadil) and ACTIS(R), two innovations in the treatment of erectile dysfunction ("ED") and has entered into a license and supply agreement with Abbott Laboratories ("Abbott") (NYSE:ABT) for the international marketing and distribution of its male transurethral ED products. In Canada, VIVUS has entered into a license and supply agreement with Paladin Labs, Inc. ("Paladin") (TSE:PLB) by which Paladin will market and distribute MUSE. VIVUS has ongoing research and development ("R&D") programs in male ED, female sexual dysfunction ("FSD"), and male premature ejaculation ("PE"). Adding to the Company's R&D pipeline in the first quarter of 2001, VIVUS

licensed from TANABE SEIYAKU CO, LTD. ("TANABE"), a leading Japanese pharmaceutical company, TANABE's proprietary phosphodiesterase type 5 (PDE5) inhibitor compound TA-1790 for both the oral and local treatment of male and female sexual dysfunction. In January 2001, the Company began enrolling patients in a multi-center clinical study for its female sexual dysfunction product, ALISTA(TM), intended to evaluate the sexual response in women with a primary diagnosis of Female Sexual Arousal Disorder ("FSAD").

During 1998, the Company experienced a significant decline (greater than 80%) in market demand for MUSE as a result of the introduction of Viagra in April 1998. During the second and third quarters of 1998, the Company took significant steps to restructure its operations to bring its cost structure in line with current and projected revenues. As a result, the Company incurred a net loss of \$80 million and had negative operating cash flow of approximately \$27 million for the year ended December 31, 1998.

During 1999, the Company continued to align its operations more closely with the Company's current and expected revenues. The Company achieved profitability for all quarters in 1999, earning \$0.58 per diluted share for the year. Cash, cash equivalents and available-for-sale securities at December 31, 1999 increased \$16.5 million from December 31, 1998 to \$40.4 million, while total liabilities decreased \$5.1 million during the same period. The Company was awarded five patents in the areas of FSD, ED and PE to further build and strengthen its patent portfolio. The Company established a targeted sales force in the U.S. to support its product, MUSE, in the marketplace. The Company also filed a New Drug Application ("NDA") for ALIBRA with the Food and Drug Administration ("FDA") that was subsequently withdrawn in October 2000.

During 2000, the Company continued to strengthen its balance sheet, increasing working capital by \$6.4 million, to enable investment in its R&D projects and to pursue targeted technology acquisitions to expand its pipeline. The Company filed an Investigational New Drug ("IND") application and began clinical studies for ALISTA, its product for the treatment of FSD. The Company signed an agreement with Abbott for the marketing of MUSE internationally, except Canada, where Paladin is marketing and distributing MUSE. The Company was awarded several new patents for the treatment of ED and solidified its FSD intellectual property through its agreement with AndroSolutions. The Company also received 510(k) clearance from the FDA in December 2000, for over-the-counter (OTC) marketing of ACTIS, its adjustable constriction band used to improve erections in men with ED.

#### HIGHLIGHTS

In January 2001, the Company signed a development, license and supply agreement with TANABE for its proprietary phosphodiesterase type 5 (PDE5) inhibitor compound TA-1790 for the oral and local treatment of male and female sexual dysfunction. TA-1790 is a relatively fast acting, highly selective, potent PDE5 inhibitor. TA-1790 has important characteristics that the Company believes may provide advantages enabling VIVUS to compete successfully in the first line oral ED market. This compound also provides the Company with the opportunity to develop other products, such as a new generation of potentially more effective locally delivered products for both male and female sexual dysfunction.

The Company filed an IND application with the FDA for its FSD product, ALISTA, and began enrollment for the initial clinical study in October 2000. In January 2001, enrollment began in a multi-center Phase II study to evaluate the safety and efficacy of ALISTA in women with a primary diagnosis of FSAD.

The Company signed a distribution and marketing agreement granting Abbott exclusive rights for MUSE covering all international markets outside the U.S. and Canada. In addition, Abbott obtained rights to ALIBRA, pending regulatory approval, in all international markets as well as the option to co-develop and license future transurethral products for the treatment of ED internationally. The company manufactured and shipped product to Abbott within three months of the signing of the distribution agreement. Abbott has re-launched MUSE in the United Kingdom, Ireland, Sweden, Switzerland, Denmark, Germany, New Zealand, Australia, Norway and Finland as of March 2001.

The Company granted Paladin the exclusive right to distribute and market MUSE in Canada and began shipping MUSE to Paladin in February 2001.

The Company was awarded three new patents by the U.S. Patent & Trademark Office. The first provides the Company with broad patent protection for commercializing locally delivered PDE5 inhibitors, including combinations with other active agents, for the treatment of ED. The second provides broad patent protection for oral, topical, transdermal and transurethral administration of serotonin antagonists, specifically 5-HT3 antagonists, to treat PE in men. The third provides the Company with broad patent protection for commercializing local delivery of PDE4 inhibitors, including combinations with other active agents, for the treatment of ED.

The Company conducted a proof-of-concept study with an oral drug for the treatment of PE and is conducting formulation work to optimize the drug product. Additional clinical trials will be initiated upon completion of this formulation work.

The Company filed for marketing authorization with the European Agency for the Evaluation of Medicinal Products ("EMEA") for ALIBRA, its second-generation transurethral product for the treatment of ED. In October 2000, the Company withdrew its NDA for ALIBRA filed with the FDA in 1999. The Company continues to communicate with the FDA and EMEA to determine what additional data is required to obtain marketing clearance for ALIBRA.

The Company received 510(k) clearance from the FDA for over-the-counter marketing of ACTIS, an adjustable constriction band designed to improve erections in men with ED.

#### RESULTS OF OPERATIONS

Years Ended December 31, 2000 and 1999

U.S. product revenues for the year ended December 31, 2000 were \$22.5 million, remaining relatively flat as compared to \$21.2 million for the year ended December 31, 1999.

International revenue was \$5.2 million for the year ended December 31, 2000, compared to \$20.0 million for the same period in 1999. The \$20.0 million in revenues reported in 1999 included \$14.9 million associated with the termination of the Company's distribution agreement with AstraZeneca.

In 1999, the Company recorded a \$9.1 million charge for the actual and anticipated return of expired product in the U.S. These returns were primarily the result of shipments made during the fourth quarter of 1997 and the first quarter of 1998. Demand for MUSE declined following the launch of Viagra in April 1998, resulting in excess inventories at wholesalers and retailers. In 2000, the charge for actual and anticipated returns of product was \$1.2 million, or five percent of gross sales.

Cost of goods sold for the year ended December 31, 2000 was \$8.1 million, compared to \$12.4 million for the same period in 1999. A portion of this decline is a result of the Company recording a \$3.1 million write-up of its raw material inventory that had been previously reserved in 1998. In addition, the Company reversed an accrual for royalties of \$2.0 million related to shipments to its previous international distributors due to the termination of those distribution agreements.

R&D expenses for the year ended December 31, 2000 were \$4.7 million, compared to \$7.9 million in the year ended December 31, 1999. The \$3.2 million decrease is a result of lower spending in 2000 versus 1999 when the Company was completing its Phase III clinical studies and filing an NDA for ALIBRA.

Selling, general and administrative expenses for the year ended December 31, 2000 were \$8.7 million, compared to \$6.3 million in the year ended December 31, 1999. The increased expenses in 2000 were primarily a result of the Company's additional investment in its U.S. marketing and sales effort.

Operating expenses for the year ended December 31, 2000 includes a reversal of \$903 thousand of restructuring reserve established in 1998 related primarily to inventory commitments and other manufacturing expenses that were not required. Operating expenses for the year ended December 31, 1999 include a non-cash

charge of \$600,000 for the issuance of 120,000 shares of common stock toward the settlement of shareholders class action lawsuits. The Company also reclassified \$1.8 million in 1999 from other restructuring costs to the allowance for product returns during earlier quarters.

The Company recorded a tax provision of ten percent of net income before taxes for 2000. The effective tax rate calculation includes the effect of net operating losses ("NOLs") carried forward from prior periods. The tax rate would have been substantially higher if the NOLs had not been available to offset current income. The Company recorded a tax provision of five percent of net income before taxes for 1999.

#### Years Ended December 31, 1999 and 1998

Product revenues for the year ended December 31, 1999 were \$21.2 million in the U.S. and \$20.0 million internationally, compared to \$39.0 million in the U.S. and \$32.7 million internationally for the same period in 1998. The significant decline in U.S. product revenue is due to lower demand for the Company's product MUSE, which resulted from the launch of Viagra, a competitive oral treatment for ED. The international revenue decrease from 1998 is mainly attributable to reduced orders from both AstraZeneca and Janssen, the Company's previous international distribution partners of MUSE.

For the year ended December 31, 1999, the Company recorded \$8 million in milestone revenue from AstraZeneca related to regulatory approvals of MUSE in France, Germany, Italy and Spain. For the year ended December 31, 1998, the Company recorded \$3 million in milestone revenue from Janssen related to regulatory approvals of MUSE in South Korea and Canada.

Total revenue in 1999 also included \$3.1 million in other revenue associated with the return of marketing and distribution rights for MUSE from AstraZeneca. Additionally, the Company recorded a \$9.1 million charge for the actual and anticipated return of expired product in the U.S. These returns are primarily the result of shipments made during the fourth quarter of 1997 and the first quarter of 1998. Demand for MUSE declined following the launch of Viagra in April 1998, resulting in excess inventories at wholesalers and retailers.

Cost of goods sold for the year ended December 31, 1999 was \$12.4 million, compared to \$55.6 million for the same period in 1998. The decrease was primarily a result of lower unit shipments in 1999. In addition, an inventory valuation reserve of \$16.0 million was recorded in 1998.

Research and development (R&D) expenses for the year ended December 31, 1999 were \$7.9 million, compared to \$16.2 million in the year ended December 31, 1998. Lower spending in 1999 was primarily a result of the Company's effort to bring overall cost levels in line with the Company's current and projected revenues. Higher spending in 1998 was mainly associated with a significantly larger R&D organization.

Selling, general and administrative expenses for the year ended December 31, 1999 were \$6.3 million, compared to \$40.5 million in the year ended December 31, 1998. The lower expenses in 1999 were primarily a result of the Company's effort to bring overall cost levels in line with the Company's projected future demand for MUSE. Included in selling, general and administration expenses for 1998 were significant expenses for a direct-to-consumer advertising campaign as well as a direct sales force, which the Company did not incur in 1999.

Operating expenses for the year ended December 31, 1999 included a non-cash charge of \$600,000 for the issuance of 120,000 shares of common stock toward the settlement of shareholders class action lawsuits. In addition, the Company reclassified \$1.8 million from other restructuring costs during the fourth quarter to allowance for product returns during earlier quarters. Operating expenses for the year ended December 31, 1998 included a restructuring charge of \$12.5 million, primarily associated with the sales force and other personnel reductions; and a \$32.2 million write-down of property and equipment. The write-down was calculated in accordance with the provisions of Statement of Financial Accounting Standards No. 121 and represents the excess of the carrying values of property and equipment over the projected future discounted cash flows for the Company.

The Company recorded a tax provision of five percent of net income before taxes for 1999. The effective tax rate calculation includes the effect of NOLs carried forward from prior periods. The tax rate would have been substantially higher if the NOLs had not been available to offset current income. The Company had no tax provision for 1998 as a result of the loss recorded for this year.

#### LIQUIDITY AND CAPITAL RESOURCES

Since inception, the Company has financed operations primarily from the sale of preferred and common stock. Through December 31, 2000, VIVUS raised \$154.4 million from financing activities and had an accumulated deficit of \$83.3 million at December 31, 2000.

Cash, cash equivalents and available-for-sale securities totaled \$45.3 million (including restricted cash) at December 31, 2000, compared with \$40.4 million at December 31, 1999. The \$4.9 million increase during 2000 was primarily the result of net cash provided by operating activities of \$4.5 million.

The Company issued an irrevocable standby letter of credit for \$3.3 million during the fourth quarter of 2000, in connection with its leased manufacturing facilities. The Company purchased a certificate of deposit as collateral for this letter of credit, which is restricted and not available for use in operations, and is presented accordingly as "restricted cash" in the non-current asset section of the balance sheet. This restriction will remain through the end of the lease term, including any renewals. The Company has exercised its first option to renew the original lease, thereby extending its commitment to 2007. The second renewal term, if exercised, would then extend the lease for an additional five years, to 2012.

Accounts receivable net at December 31, 2000 were \$3.4 million, compared with \$4.4 million at December 31, 1999, a decrease of \$998 thousand due primarily to lower sales and improved collections.

Total liabilities were \$19.0 million at December 31, 2000, compared with \$27.3 million at December 31, 1999, a decrease of \$8.3 million. This decrease relates primarily to payments made associated with the restructuring reserve of \$3.9 million, net returns of expired product of \$2.3 million, and a \$2.0 million reversal of royalties accrued that relate to shipments to the Company's previous international distributors due to the termination of those distribution agreements.

The Company anticipates that its existing capital resources combined with anticipated future cash flows will be sufficient to support the Company's operating needs throughout 2001. However, the Company anticipates that it will be required to obtain additional financing to fund the development of its R&D pipeline in future periods in addition to the possible launch of any future products.

The Company expects to evaluate potential financing sources, including, but not limited to, the issuance of additional equity or debt securities, corporate alliances, joint ventures, and licensing agreements to fund the development and possible commercial launch of its future products. The sale of additional equity securities would result in additional dilution to the Company's stockholders. The Company's working capital and additional funding requirements will depend upon numerous factors, including: (i) the progress of the Company's R&D programs; (ii) the timing and results of pre-clinical testing and clinical trials; (iii) results of operations; (iv) demand for MUSE; (v) technological advances; (vi) the level of resources that the Company devotes to sales and marketing capabilities; and (vii) the activities of competitors.

#### ITEM 7A. QUANTITATIVE AND QUALITATIVE DISCLOSURES ABOUT MARKET RISK

The SEC's rule related to market risk disclosure requires that the Company describe and quantify its potential losses from market risk sensitive instruments attributable to reasonably possible market changes. Market risk sensitive instruments include all financial or commodity instruments and other financial instruments that are sensitive to future changes in interest rates, currency exchange rates, commodity prices or other market factors. The Company is not exposed to market risks from changes in foreign currency exchange rates or commodity prices. The Company does not hold derivative financial instruments nor does it hold securities for trading or speculative purposes. At December 31, 1999 and 2000, the Company had no debt outstanding, and consequently the Company currently has no risk exposure associated with increasing interest rates. The Company, however, is exposed to changes in interest rates on its investments in cash equivalents

and available-for-sale securities. Substantially all of its investments in cash equivalents and available-for-sale securities are in money market funds that hold short-term investment grade commercial paper, treasury bills or other U.S. government obligations. Currently, this reduces the Company's exposure to long-term interest rate changes.

This Form 10-K contains "forward-looking" statements about future financial results, future products and other events that have not yet occurred. For example, statements like we "expect," we "anticipate" or we "believe" are forward-looking statements. Investors should be aware that actual results may differ materially from our expressed expectations because of risks and uncertainties about the future. We will not necessarily update the information in this Form 10-K if any forward-looking statement later turns out to be inaccurate. Details about risks affecting various aspects of our business are discussed throughout this Form 10-K. Investors should read all of these risks carefully, and should pay particular attention to risks affecting the following areas: new product development and uncertainty of product approvals (pages 10 and 11); intense competition (page 11); future capital needs and uncertainty of additional financing (pages 11 and 12); limited sales and marketing in the U.S. (page 12); dependence on third parties (pages 12 and 13); raw materials (page 13); single manufacturing facility (page 13); and other risk factors as stated (pages 10 through 18).

## ITEM 8. FINANCIAL STATEMENTS AND SUPPLEMENTARY DATA

## VIVUS, INC.

## 1. INDEX TO CONSOLIDATED FINANCIAL STATEMENTS

The following financial statements are filed as part of this Report:

	PAGE
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Report of independent public accountants.....	30
Consolidated Balance Sheets as of December 31, 2000 and 1999.....	31
Consolidated Statements of Operations for the years ended December 31, 2000, 1999 and 1998.....	32
Consolidated Statements of Stockholders' Equity for the years ended December 31, 2000, 1999 and 1998.....	33
Consolidated Statements of Cash Flows for the years ended December 31, 2000, 1999 and 1998.....	34
Notes to Consolidated Financial Statements.....	35

## REPORT OF INDEPENDENT PUBLIC ACCOUNTANTS

To the Stockholders and Board of Directors of VIVUS, Inc.:

We have audited the accompanying consolidated balance sheets of VIVUS, Inc. (a Delaware corporation) and subsidiaries as of December 31, 2000 and 1999, and the related consolidated statements of operations, stockholders' equity and cash flows for each of the three years in the period ended December 31, 2000. These financial statements are the responsibility of the Company's management. Our responsibility is to express an opinion on these financial statements based on our audits.

We conducted our audits in accordance with auditing standards generally accepted in the United States. Those standards require that we plan and perform the audit to obtain reasonable assurance about whether the financial statements are free of material misstatement. An audit includes examining, on a test basis, evidence supporting the amounts and disclosures in the financial statements. An audit also includes assessing the accounting principles used and significant estimates made by management, as well as evaluating the overall financial statement presentation. We believe that our audits provide a reasonable basis for our opinion.

In our opinion, the financial statements referred to above present fairly, in all material respects, the financial position of VIVUS, Inc. and subsidiaries at December 31, 2000 and 1999, and the results of their operations and their cash flows for each of the three years in the period ended December 31, 2000, in conformity with accounting principles generally accepted in the United States.

/s/ ARTHUR ANDERSEN LLP

San Jose, California  
January 18, 2001

## VIVUS, INC.

CONSOLIDATED BALANCE SHEETS  
(IN THOUSANDS, EXCEPT PAR VALUE)

## ASSETS

	DECEMBER 31,	
	2000	1999
Current assets:		
Cash and cash equivalents.....	\$ 29,236	\$ 8,785
Available-for-sale securities.....	9,187	27,049
Accounts receivable (net of allowance for doubtful accounts of \$304 and \$147 at December 31, 2000 and 1999).....	3,434	4,432
Inventories, net.....	5,045	3,527
Prepaid expenses and other assets.....	1,143	4,338
Total current assets.....	48,045	48,131
Property and equipment, net.....	14,294	16,071
Restricted cash.....	3,324	--
Available-for-sale securities, non-current.....	3,511	4,558
Total assets.....	\$ 69,174	\$ 68,760
	=====	=====
LIABILITIES AND STOCKHOLDERS' EQUITY		
Current liabilities:		
Accounts payable.....	\$ 1,775	\$ 2,453
Accrued and other liabilities.....	13,289	19,062
Total current liabilities.....	15,064	21,515
Accrued and other long-term liabilities.....	3,923	5,749
Total liabilities.....	18,987	27,264
Stockholders' equity:		
Common stock; \$.001 par value; shares authorized -- 200,000 at December 31, 2000 and 1999; shares outstanding -- December 31, 2000, 32,461 December 31, 1999, 32,211.....	32	32
Paid in capital.....	133,288	132,643
Accumulated other comprehensive income.....	165	(190)
Accumulated deficit.....	(83,298)	(90,989)
Total stockholders' equity.....	50,187	41,496
Total liabilities and stockholders equity.....	\$ 69,174	\$ 68,760
	=====	=====

The accompanying notes are an integral part of these financial statements.

## VIVUS, INC.

CONSOLIDATED STATEMENTS OF OPERATIONS  
(IN THOUSANDS, EXCEPT PER SHARE DATA)

	YEAR ENDED DECEMBER 31,		
	2000	1999	1998
Revenue			
US product.....	\$22,474	\$21,168	\$ 39,041
International product.....	5,200	19,996	32,658
Milestone.....	--	8,000	3,000
Other revenue.....	--	3,142	--
Returns.....	(1,181)	(9,118)	--
Total revenue.....	26,493	43,188	74,699
Cost of goods sold.....	8,066	12,369	55,616
Gross profit.....	18,427	30,819	19,083
Operating expenses:			
Research and development.....	4,670	7,884	16,178
Selling, general and administrative.....	8,655	6,332	40,477
Settlement of lawsuits.....	--	600	--
Write-down of property.....	--	--	32,163
Other restructuring costs.....	(903)	(1,793)	12,490
Total operating expenses.....	12,422	13,023	101,308
Income (loss) from operations.....	6,005	17,796	(82,225)
Interest and other income.....	2,541	1,994	1,972
Income (loss) before provision for income taxes.....	8,546	19,790	(80,253)
Provision for income taxes.....	(855)	(989)	--
Net income (loss).....	\$ 7,691	\$18,801	\$(80,253)
Net income (loss) per share:			
Basic.....	\$ 0.24	\$ 0.59	\$ (2.52)
Diluted.....	\$ 0.23	\$ 0.58	\$ (2.52)
Shares used in per share computation:			
Basic.....	32,328	32,085	31,876
Diluted.....	33,428	32,507	31,876

The accompanying notes are an integral part of these financial statements.

## VIVUS, INC.

CONSOLIDATED STATEMENTS OF STOCKHOLDERS' EQUITY  
(IN THOUSANDS)

	COMMON STOCK AND PAID IN CAPITAL		ACCUMULATED OTHER COMPREHENSIVE INCOME	ACCUMULATED DEFICIT	TOTAL
	SHARES	AMOUNT			
Balances, December 31, 1997.....	33,168	\$153,369	\$ 98	\$ (29,537)	\$123,930
Sale of common stock through employee stock purchase plan.....	77	489			489
Exercise of common stock options for cash.....	288	576			576
Repurchase of common stock for cash.....	(1,663)	(23,584)			(23,584)
Stock compensation costs.....	20	648			648
Unrealized loss on securities...			(129)		(129)
Net (loss).....				(80,253)	(80,253)
Balances, December 31, 1998.....	31,890	131,498	(31)	(109,790)	21,677
Sale of common stock through employee stock purchase plan.....	97	208			208
Exercise of common stock options for cash.....	104	188			188
Settlement of lawsuits.....	120	600			600
Stock compensation costs.....		181			181
Unrealized loss on securities...			(159)		(159)
Net income.....				18,801	18,801
Balances, December 31, 1999.....	32,211	132,675	(190)	(90,989)	41,496
Sale of common stock through employee stock purchase plan.....	117	276			276
Exercise of common stock options for cash.....	133	369			369
Unrealized gain on securities...			355		355
Net income.....				7,691	7,691
Balances, December 31, 2000.....	32,461	\$133,320	\$ 165	\$ (83,298)	\$ 50,187

The accompanying notes are an integral part of these financial statements.

## VIVUS, INC.

CONSOLIDATED STATEMENTS OF CASH FLOWS  
(IN THOUSANDS)

	YEAR ENDED DECEMBER 31,		
	2000	1999	1998
<b>CASH FLOWS FROM OPERATING ACTIVITIES:</b>			
Net income (loss).....	\$ 7,691	\$ 18,801	\$ (80,253)
Adjustments to reconcile net income (loss) to net cash provided by (used for) operating activities:			
Depreciation and amortization.....	2,379	3,316	3,688
Property write-down.....	--	--	32,163
Inventory write-down.....	--	--	16,083
Stock compensation costs.....	--	181	648
Settlement of lawsuits.....	--	600	--
Changes in assets and liabilities:			
Accounts receivable.....	998	765	6,594
Inventories.....	(1,518)	1,745	(12,271)
Prepaid expenses and other assets.....	3,195	(3,804)	1,102
Accounts payable.....	(678)	(824)	(3,297)
Accrued and other liabilities.....	(7,599)	(4,344)	8,989
Net cash provided by (used for) operating activities.....	4,468	16,436	(26,554)
<b>CASH FLOWS FROM INVESTING ACTIVITIES:</b>			
Property and equipment purchases.....	(602)	(173)	(18,602)
Investment in restricted certificate of deposit.....	(3,324)	--	--
Investment purchases.....	(120,941)	(134,860)	(180,791)
Proceeds from sale/maturity of securities.....	140,205	123,997	245,294
Net cash provided by (used for) investing activities.....	15,338	(11,036)	45,901
<b>CASH FLOWS FROM FINANCING ACTIVITIES:</b>			
Sale of common stock through employee stock purchase plan.....	276	208	489
Exercise of common stock options.....	369	188	576
Repurchase of common stock.....	--	--	(23,584)
Net cash provided by (used for) financing activities.....	645	396	(22,519)
NET INCREASE (DECREASE) IN CASH.....	20,451	5,796	(3,172)
<b>CASH:</b>			
Beginning of year.....	8,785	2,989	6,161
End of year.....	\$ 29,236	\$ 8,785	\$ 2,989
<b>NON-CASH INVESTING AND FINANCING ACTIVITIES:</b>			
Unrealized gain (loss) on securities.....	\$ 355	\$ (159)	\$ (129)
<b>SUPPLEMENTAL CASH FLOW DISCLOSURE:</b>			
Income taxes paid.....	\$ 532	\$ 36	\$ 71

The accompanying notes are an integral part of these financial statements.

## VIVUS, INC.

## NOTES TO CONSOLIDATED FINANCIAL STATEMENTS

## NOTE 1. BUSINESS AND SIGNIFICANT ACCOUNTING POLICIES

## BUSINESS

VIVUS, Inc. (the "Company") was incorporated in 1991. The Company's objective is to become a global leader in the development and commercialization of innovative therapies for the treatment of sexual dysfunction and other urologic disorders in men and women.

The Company obtained clearance from the U.S. Food and Drug Administration ("FDA") to manufacture and market MUSE, a transurethral applicator used for treating erectile dysfunction, in the United States in November 1996. The Medicines Control Agency ("MCA") approved MUSE for marketing in the United Kingdom in November 1997. MUSE has been approved in more than 40 countries around the globe.

During 1998, the Company experienced a significant decline in market demand for MUSE as the result of the introduction of Viagra in April 1998. During the second and third quarters of 1998, the Company took significant steps to restructure its operation in an attempt to bring the cost structure in line with current and projected revenues. At December 31, 2000, the Company's accumulated deficit was approximately \$83.3 million.

The Company primarily sells its products through wholesale channels in the U.S. International sales are made only to the Company's international distributors. All transactions are denominated in U.S. dollars, therefore, the Company considers the arrangement as operating in a single segment reporting to the chief executive officer.

## SIGNIFICANT ACCOUNTING POLICIES

## Principles of Consolidation

The consolidated financial statements include the accounts of VIVUS, Inc., VIVUS International Limited, a wholly-owned subsidiary, and VIVUS Ireland Limited, VIVUS UK Limited and VIVUS BV Limited, wholly-owned subsidiaries of VIVUS International Limited. All significant intercompany transactions and balances have been eliminated in consolidation.

## Use of Estimates

The preparation of financial statements in conformity with generally accepted accounting principles requires management to make estimates and assumptions that affect the reported amounts of assets and liabilities and disclosures of contingent assets and liabilities at the date of the financial statements and the reported amounts of revenues and expenses during the reporting period. Actual results could differ from those estimates.

## Cash and Cash Equivalents

The Company considers all highly liquid investments purchased with an original maturity of 90 days or less to be cash equivalents.

## Available-for-Sale Securities

Available-for-sale securities represent investments in debt securities that are stated at fair value. The difference between amortized cost (cost adjusted for amortization of premiums and accretion of discounts which are recognized as adjustments to interest income) and fair value, representing unrealized holding gains or losses, are recorded in "Accumulated Other Comprehensive Income," a separate component of stockholders' equity until realized. The Company's policy is to record investments in debt securities as available-for-sale because the sale of such securities may be required prior to maturity. Any gains and losses on the sale of debt

## NOTES TO CONSOLIDATED FINANCIAL STATEMENTS (CONTINUED)

securities are determined on a specific identification basis and are included in interest and other income in the accompanying consolidated statements of operations.

## Inventories

Inventories are stated at the lower of cost (first-in, first-out basis) or market and consist of raw materials, work in process and finished goods. Cost includes material and conversion costs. Pending FDA marketing clearance, which was obtained in November 1996, the Company expensed to research and development all raw material purchases prior to October 1, 1996. Certain of these expensed raw material costs benefited 1998 by reducing cost of sales by \$2.7 million.

During the quarter ended September 30, 1998, the Company wrote down its inventory to align with new estimates of expected future demand for MUSE. The Company had built up its inventory level prior to and after the launch of Viagra and had not anticipated the impact that Viagra would have on the demand for MUSE. The Company had anticipated sales to ultimately increase as a result of an expanding impotence market. Given the decline in demand for MUSE, in 1998 the Company recorded a valuation reserve of \$16.0 million, related to excess raw materials and future inventory purchase commitments for raw materials. This write-down is included in "cost of sales" in 1998. Based on current projections of usage, the Company recorded a \$3.1 million write up of its raw material inventory in the fourth quarter of 2000 that had been reserved in 1998.

## Prepaid Expenses and Other Assets

Prepaid expenses and other assets generally consist of deposits, prepayments for future services and other assets. Prepayments are expensed when the services are received.

## Property and Equipment

Property and equipment is stated at cost and includes machinery and equipment, computers and software, furniture and fixtures and building improvements. For financial reporting, depreciation and amortization are computed using the straight-line method over estimated useful lives of two to seven years. Leasehold improvements are amortized using the straight-line method over the lesser of the estimated useful lives or remaining lease term. Expenditures for repairs and maintenance which do not extend the useful life of the property and equipment are expensed as incurred. Upon retirement, the asset cost and related accumulated depreciation are relieved from the accompanying consolidated financial statements. Gains and losses associated with dispositions or impairment of equipment, vehicles and leasehold improvements are reflected as a component of other income, net in the accompanying consolidated statements of operations.

## Restricted Cash

The Company issued an irrevocable standby letter of credit for \$3.3 million during the fourth quarter of 2000, in connection with its leased manufacturing facilities. The Company purchased a certificate of deposit as collateral for this letter of credit, which is restricted and not available for use in operations, and is presented accordingly as restricted cash in the non-current asset section of the balance sheet. This restriction will remain through the end of the lease term, including any renewals. The Company has exercised its first option to renew the original lease, thereby extending its commitment to 2007. The second renewal term, if exercised, would then extend the lease for an additional five years, to 2012.

## Revenue Recognition

In December 1999, the Securities and Exchange Commission issued Staff Accounting Bulletin No. 101 ("SAB 101"), "Revenue Recognition in Financial Statements." SAB 101 provides guidance on applying

## NOTES TO CONSOLIDATED FINANCIAL STATEMENTS (CONTINUED)

generally accepted accounting principles to revenue recognition issues in financial statements, and became effective in the fourth quarter of 2000. The Company adopted SAB 101 in the first quarter of 2000. The adoption of SAB 101 did not have a material impact on our consolidated results of operations and financial position.

## U.S.

The Company recognizes revenue when persuasive evidence of an arrangement exists, delivery has occurred, the sales price is fixed or determinable and collectibility is probable. Generally, these criteria are met at the time the product is shipped. The Company primarily sells its products through the wholesale channel in the United States. The Company provides for an estimated cost of product returns upon shipment based on historical experience.

## International

The Company invoices its international distributors based on an agreed transfer price per unit, that is subject to revision based on contractual formulas either up or down upon quarterly reconciliations. Final pricing for product shipments to international distributors is subject to contractual formulas based on the distributor's net realized price to their customers. At the time of shipment, the Company recognizes revenue at the lowest possible price in accordance with contractual formulas and recognizes additional revenue, if any, upon finalization of pricing with its international distributors. As of December 31, 2000, the Company had deferred revenue of \$1.9 million representing amounts billed in excess of revenue recognized.

## Income Taxes

The Company uses the liability method to calculate deferred taxes. The realization of deferred tax assets is based on historical tax positions and expectations about future taxable income. Deferred income tax assets and liabilities are computed for differences between the financial statement and tax basis of assets and liabilities based on enacted tax laws and rates applicable to the period in which differences are expected to affect taxable income. Valuation allowances are established, when necessary, to reduce deferred tax assets to amounts that are more likely than not to be realized.

## License Agreements

The Company has obtained rights to patented technologies related to its initial product MUSE under several licensing agreements. These agreements generally required milestone payments during the development period and royalties on product sales. Royalties on product sales are included in cost of goods sold. The Company reversed \$2.0 million of accrued royalties in 2000 related to shipments to its previous international distributors due to the termination of those distribution agreements.

## Net Income (Loss) Per Share

Basic earnings per share ("EPS") is computed using the weighted average number of common shares outstanding during the periods. Diluted EPS is based on the weighted average number of common and common equivalent shares, which represent shares that may be issued in the future upon the exercise of

## NOTES TO CONSOLIDATED FINANCIAL STATEMENTS (CONTINUED)

outstanding stock options under the treasury stock method. The computation of basic and diluted EPS for the years ended December 31, 2000, 1999 and 1998 are as follows:

	2000	1999	1998
	-----	-----	-----
	(IN THOUSANDS, EXCEPT PER SHARE DATA)		
Net income (loss).....	\$ 7,691	\$18,801	\$(80,253)
	=====	=====	=====
Net income (loss) per share -- basic.....	\$ .24	\$ .59	\$ (2.52)
Effect of dilutive securities (stock options).....	(.01)	(.01)	--
	-----	-----	-----
Net income (loss) per share -- diluted.....	\$ .23	\$ .58	\$ (2.52)
	=====	=====	=====
Shares used in the computation of net income (loss) per share -- basic.....	32,328	32,085	31,876
Effect of dilutive securities (stock options).....	1,100	422	--
	-----	-----	-----
Diluted shares.....	33,428	32,507	31,876
	=====	=====	=====

Options to purchase 290,041 shares at prices ranging from \$5.81 to \$25.88, which were outstanding at December 31, 2000, are not included in the computation of diluted EPS for 2000 because the option prices were greater than the average market price of common shares. Options to purchase 964,879 shares at prices ranging from \$3.25 to \$25.88, which were outstanding at December 31, 1999, are not included in the computation of diluted EPS for 1999 because the option prices were greater than the average market price of common shares.

## Other Recent Pronouncements

Accounting for Derivative Instruments and Hedging Activities. The Financial Accounting Standards Board ("FASB") issued Statement of Financial Accounting Standards ("SFAS") No. 133, "Accounting for Derivative Instruments and for Hedging Activities" ("SFAS 133") and SFAS No. 138, "Accounting for Certain Derivative Instruments and Certain Hedging Activities, an amendment of FASB Statement No. 133" ("SFAS 128"), in June 1998 and June 2000, respectively. As amended, SFAS 133 establishes accounting and reporting standards for derivative instruments and hedging activities including recognizing all derivatives as either assets or liabilities in the financial statement at fair value. The adoption of SFAS 133 does not impact the Company's financial statements as the Company does not invest in derivatives or participate in hedging activities.

Accounting for Certain Transactions Involving Stock Compensation. In March 2000, the Financial Accounting Standards Board issued Interpretation No. 44 "Accounting for Certain Transactions Involving Stock Compensation -- an Interpretation of APB Opinion 25" ("FIN 44"). FIN 44 clarifies the application of APB Opinion 25 for certain matters, specifically (a) the definition of an employee for purposes of applying APB Opinion 25; (b) the criteria for determining whether a plan qualifies as a noncompensatory plan; (c) the accounting consequence of various modifications to the terms of a previously fixed stock option or award, and (d) the accounting for an exchange of stock compensation awards in a business combination. The Company adopted FIN 44 as required by July 1, 2000. The adoption of this interpretation did not have a material impact on the Company's consolidated results of operations or financial position.

## NOTE 2. AVAILABLE-FOR-SALE SECURITIES

The fair value and the amortized cost of available-for-sale securities at December 31, 2000 and 1999 are presented in the table that follows. Fair values are based on quoted market prices obtained from an independent broker. For each category of investment securities, the table presents gross unrealized holding gains and losses.

## VIVUS, INC.

## NOTES TO CONSOLIDATED FINANCIAL STATEMENTS (CONTINUED)

As of December 31, 2000 (in thousands):

	AMORTIZED COST	FAIR MARKET VALUE	UNREALIZED HOLDING GAINS	UNREALIZED HOLDING LOSSES
	-----	-----	-----	-----
U.S. government securities.....	\$ 4,484	\$ 4,598	\$ 114	\$ --
Corporate debt.....	8,049	8,100	51	--
	-----	-----	-----	-----
Total.....	12,533	12,698	165	0
Amount classified as short-term.....	(9,064)	(9,187)	(123)	--
	-----	-----	-----	-----
Amount classified as long-term.....	\$ 3,469	\$ 3,511	\$ 42	\$ 0
	=====	=====	=====	=====

As of December 31, 1999 (in thousands):

	AMORTIZED COST	FAIR MARKET VALUE	UNREALIZED HOLDING GAINS	UNREALIZED HOLDING LOSSES
	-----	-----	-----	-----
U.S. government securities.....	\$ 25,155	\$ 24,980	\$ 1	\$(176)
Corporate debt.....	6,642	6,627	2	(17)
	-----	-----	-----	-----
Total.....	31,797	31,607	3	(193)
Amount classified as short-term.....	(27,227)	(27,049)	(3)	(181)
	-----	-----	-----	-----
Amount classified as long-term.....	\$ 4,570	\$ 4,558	\$ 0	\$ (12)
	=====	=====	=====	=====

## NOTE 3. INVENTORIES

Inventories are recorded net of reserves of \$7.7 million and \$15.0 million as of December 31, 2000 and 1999, respectively, and consist of (in thousands):

	2000	1999
	-----	-----
Raw materials.....	\$3,497	\$2,038
Work in process.....	61	143
Finished goods.....	1,487	1,346
	-----	-----
Inventory, net.....	\$5,045	\$3,527
	=====	=====

## NOTE 4. PROPERTY AND EQUIPMENT

Property and equipment as of December 31 consists of (in thousands):

	2000	1999
	-----	-----
Machinery and equipment.....	\$ 18,990	\$ 18,755
Computers and software.....	4,095	3,935
Furniture and fixtures.....	2,247	2,195
Building Improvements.....	11,839	11,714
	-----	-----
	37,171	36,599
Accumulated depreciation and amortization.....	(22,877)	(20,528)
	-----	-----
Property and equipment, net.....	\$ 14,294	\$ 16,071
	=====	=====

For the years ended December 31, 2000, 1999 and 1998, depreciation expense, in thousands, was \$2,379, \$3,316 and \$3,688, respectively.

## NOTES TO CONSOLIDATED FINANCIAL STATEMENTS (CONTINUED)

## NOTE 5. ACCRUED AND OTHER LIABILITIES

Accrued and other liabilities as of December 31 consist of (in thousands):

	2000	1999
	-----	-----
Restructuring.....	\$ 4,266	\$ 8,185
Product returns.....	2,008	4,300
Income taxes.....	3,332	3,016
Research and clinical expenses.....	2,076	2,803
Royalties.....	541	2,312
Unearned revenue.....	1,917	1,930
Employee compensation and benefits.....	1,670	1,286
Other.....	1,402	979
	-----	-----
	17,212	24,811
Amount classified as short-term.....	(13,289)	(19,062)
	-----	-----
Amount classified as long-term.....	\$ 3,923	\$ 5,749
	=====	=====

In 2000, the Company recorded a provision for product returns of \$1.2 million related to expired products. Actual returns of expired product were \$3.6 million. At December 31, 2000, a balance of \$2.0 million remained to offset anticipated future returns.

## NOTE 6. RESTRUCTURING AND RELATED CHARGES

During the second quarter of 1998, the Company recorded restructuring and related costs of \$6.5 million. The charge included costs of \$3.2 million resulting from the termination of certain marketing and promotional programs, a provision of \$2.3 million for reductions in the Company's workforce that includes severance compensation and benefit costs, and \$1.0 million in write-down of fixed assets.

During the third quarter of 1998, the Company took additional steps to restructure its operations and recorded \$54.2 million of costs and write-downs. These charges included a \$16.0 million write-down of inventory, primarily raw materials and commitments to buy raw materials, a \$32.2 million write-down in property, and \$6.0 million of other restructuring costs primarily related to personnel costs and operating lease commitments. These write-downs were calculated in accordance with the provisions of SFAS No. 121 and represents the excess of the carrying value of property and equipment, primarily the Company's New Jersey manufacturing leaseholds and equipment, over the projected future discounted cash flows for the Company.

During first quarter, second quarter and third quarter 1999, the Company included expired products returns of \$500 thousand, \$1 million, and \$293 thousand, respectively, against the "Other" restructuring. In the fourth quarter 1999, the Company reclassified these charges to returns reserve to offset product revenues, and reversed the "Other" restructuring reserve from operating expenses as such reserves were determined to be excess in 1999.

## NOTES TO CONSOLIDATED FINANCIAL STATEMENTS (CONTINUED)

Restructuring and related charges in fiscal 2000, 1999 and 1998 (in thousands):

	SEVERANCE AND EMPLOYEE COSTS	INVENTORY AND RELATED COMMITMENTS	PROPERTY AND RELATED COMMITMENTS	MARKETING COMMITMENTS	OTHER	TOTAL
	-----	-----	-----	-----	-----	-----
Restructuring Provision.....	\$ 3,069	\$ 16,083	\$ 34,684	\$ 3,191	\$ 3,708	\$ 60,735
Activity in 1998.....	(1,159)	(10,699)	(30,020)	(1,884)	(1,915)	(45,677)
	-----	-----	-----	-----	-----	-----
Balance at December 31, 1998.....	1,910	5,384	4,664	1,307	1,793	15,058
Activity in 1999.....	(1,610)	(1,379)	(784)	(1,307)	(1,793)	(6,873)
	-----	-----	-----	-----	-----	-----
Balance at December 31, 1999.....	300	4,005	3,880	0	0	8,185
Activity in 2000.....	(300)	(3,063)	(556)	--	--	(3,919)
	-----	-----	-----	-----	-----	-----
Balance at December 31, 2000.....	\$ 0	\$ 942	\$ 3,324	\$ 0	\$ 0	\$ 4,266
	=====	=====	=====	=====	=====	=====

The Company expects that during the fiscal year 2001 it will make cash payments of approximately \$400 thousand related to the restructuring, with the remaining \$3.9 million in cash payments to occur in later years.

## NOTE 7. STOCKHOLDERS' EQUITY

## Common Stock

The Company is authorized to issue 200 million shares of common stock. As of December 31, 2000 and 1999, there were 32,461,457, and 32,210,500 shares, respectively, issued and outstanding.

The Company's Board of Directors approved a stock repurchase program in May 1997 whereby the Company could purchase up to two million shares of its common stock. During 1997 the Company repurchased 336,700 shares at a cost of \$7,716,000 and during 1998 the Company repurchased 1,663,300 additional shares of its common stock at a cost of \$23,583,990.

During 1999, the Company reached a settlement of the shareholder class action lawsuits, in which the company incurred a non-cash expense of \$600,000 for the issuance of 120,000 shares of VIVUS, Inc. common stock.

## Preferred Stock

The Company is authorized to issue 5,000,000 shares of undesignated preferred stock with a par value of \$1.00 per share. As of December 31, 2000 and 1999 there are no preferred shares issued or outstanding. The Company may issue shares of preferred stock in the future, without stockholder approval, upon such terms as the Company's Board of Directors may determine.

## NOTE 8. STOCK OPTION AND PURCHASE PLANS

## Stock Option Plans

Under the 1991 Incentive Stock Plan (the Plan), the Company may grant incentive or non-statutory stock options or stock purchase rights (SPRs). Up to 7,800,000 shares of common stock have been authorized for issuance under the Plan. The Plan allows the Company to grant incentive stock options (ISOs) to employees and non-statutory stock options (NSOs) to employees, directors and consultants at not less than the fair market value (for an ISO) of the stock at the date of grant (110% of fair market value for individuals who control more than 10% of the Company stock; otherwise, not less than 85% of fair market value for an NSO), as determined by the Board of Directors. Under the Plan, 25% of the options generally become exercisable after one year and 2.0833% per month thereafter. The term of the option is determined by the Board of Directors on the date of grant but shall not be longer than ten years. The Plan allows the Company to grant SPRs to employees and consultants at not less than 85% of the fair market value of the stock at the date



## NOTES TO CONSOLIDATED FINANCIAL STATEMENTS (CONTINUED)

of grant, as determined by the Board of Directors. Sales of stock under SPRs are made pursuant to restricted stock purchase agreements containing provisions established by the Board of Directors. The Company has a right to repurchase the shares at the original sale price, which expires at a rate to be determined by the Board of Directors. As of December 31, 2000, no SPRs have been granted under the Plan.

Under the 1994 Director Option Plan (the Director Option Plan), the Company reserved 400,000 shares of common stock for issuance to non-employee directors of the Company pursuant to non-statutory stock options issued at the fair market value of the Company's common stock at the date of grant. Under the Director Option Plan, non-employee directors will receive an option to purchase 32,000 shares of common stock when they join the Board of Directors. These options vest 25% after one year and 25% annually thereafter. Each director shall receive an option to purchase 8,000 shares of the Company's common stock annually upon their reelection. These options are fully exercisable ratably over eight months.

Details of option activity under these plans are as follows:

	NUMBER OF SHARES	WEIGHTED AVERAGE EXERCISE PRICE
	-----	-----
Outstanding, December 31, 1997.....	4,521,195	\$13.57
Granted.....	1,093,338	4.96
Exercised.....	(379,375)	4.23
Cancelled.....	(2,163,416)	14.23
Repricing cancellation.....	(1,910,523)	15.16
Repricing issuance.....	1,910,523	3.42
Outstanding, December 31, 1998.....	3,071,742	\$ 3.90
Granted.....	300,783	3.36
Exercised.....	(103,623)	2.13
Cancelled.....	(324,626)	7.43
Outstanding, December 31, 1999.....	2,944,276	\$ 3.52
Granted.....	579,660	4.90
Exercised.....	(133,166)	2.77
Cancelled.....	(155,815)	3.19
Outstanding, December 31, 2000.....	3,234,955	\$ 3.81
	=====	=====

OPTIONS OUTSTANDING			OPTIONS EXERCISABLE		
RANGE OF EXERCISE PRICES	NUMBER OUTSTANDING AT DECEMBER 31, 2000	WEIGHTED-AVERAGE REMAINING CONTRACTUAL LIFE	WEIGHTED-AVERAGE EXERCISE PRICE	NUMBER EXERCISABLE DECEMBER 31, 2000	WEIGHTED-AVERAGE EXERCISE PRICE
-----	-----	-----	-----	-----	-----
\$0.24 - \$ 2.69	935,802	6.4 years	\$2.07	581,860	\$1.76
\$2.72 - \$ 3.38	821,942	5.6 years	\$2.96	717,445	\$2.94
\$3.75 - \$ 4.50	812,079	6.2 years	\$4.31	597,096	\$4.38
\$4.84 - \$25.88	665,132	7.5 years	\$6.71	250,888	\$8.60
	-----			-----	
\$0.24 - \$25.88	3,234,955	6.4 years	\$3.81	2,147,289	\$3.68
	=====			=====	

At December 31, 2000, 2,789,999 options remain available for grant.

During 1997, options to purchase 100,000 shares of common stock were granted to research consultants at the fair market value on the date of grant. Compensation costs, including the impact of re-pricing, using the Black-Scholes option-pricing model approximately \$1.1 million over the option's vesting period

of which \$181,000 and \$648,000 were recorded as expenses for the years ended December 31, 1999 and 1998, respectively. These options were cancelled in July 1999, when the Company decided not to renew the contract

## NOTES TO CONSOLIDATED FINANCIAL STATEMENTS (CONTINUED)

with the research consultants. The research consultants exercised a total of 25,000 shares of these options during 1999.

In October 1998, the Company's Board of Directors authorized the re-pricing of all non-executive employees' options, certain consultants' options, and 50% of executives' options to the closing value as of October 19, 1998. The remaining 50% of executive options were re-priced at 150% of the closing value as of the same date.

As permitted under SFAS No. 123, the Company accounts for these plans under APB Opinion No. 25. Except for compensation as discussed above, no compensation cost has been recognized because the exercise price equals the market value of stock on the date of grant. Options under these plans generally vest over four years, and all options expire after ten years.

Under FASB Statement No. 123 (FASB 123), "Accounting for Stock-based Compensation," the estimated fair value of options is amortized to expense over the options' vesting period. In accordance with the disclosure requirements of FASB 123, if the Company had elected to recognize this expense, income (loss) and income (loss) per share would have been reduced to the following pro forma amounts (in thousands, except per share data):

	2000	1999	1998
	-----	-----	-----
Pro forma net income (loss).....	\$6,509	\$17,341	\$(83,129)
Pro forma net income (loss) per share:			
Basic.....	\$ 0.20	\$ 0.54	\$ (2.61)
Diluted.....	\$ 0.19	\$ 0.53	\$ (2.61)

The fair value of each option grant is estimated on the date of grant using the Black-Scholes option pricing model with the following assumptions used for grants: risk-free rates ranging from 5 - 6% and corresponding to government securities with original maturities similar to the vesting periods; expected dividend yield of 0%; expected lives of .64 years beyond vest dates; and expected volatility of 55% in all years.

#### Stock Purchase Plan

Under the 1994 Employee Stock Purchase Plan (the Stock Purchase Plan), the Company reserved 800,000 shares of common stock for issuance to employees pursuant to the Stock Purchase Plan, under which eligible employees may authorize payroll deductions of up to 10% of their base compensation (as defined) to purchase common stock at a price equal to 85% of the lower of the fair market value as of the beginning or the end of the offering period. As of December 31, 2000, 386,963 shares have been issued to employees and there are 413,037 available for issuance. During 2000, the weighted average fair market value of shares issued under the Stock Purchase Plan was \$2.32 per share.

#### NOTE 9. LICENSE AGREEMENTS

The Company has entered into several agreements to license patented technologies that are essential to the development and production of the Company's transurethral products for the treatment of ED. In connection with these agreements, upon meeting certain milestones (as defined) and contingent on the issuance of patents in certain countries, the Company was obligated to (i) pay license fees of \$2,575,000 (of which \$2,175,000 was paid prior to December 31, 1997 and \$400,000 was paid in January 1998); (ii) issue 896,492 shares of the Company's common stock (all of which has been issued); and (iii) pay royalties on product sales covered by the license agreements (4% of U.S. and Canadian product sales and 3% of sales elsewhere in the world). In 1996, the Company issued an additional 400,000 shares of common stock to maintain exclusive rights to certain patents and patent applications beyond 1998. In 1998, 1999 and 2000, the Company recorded royalty expenses as cost of goods sold based on product sales.

## NOTES TO CONSOLIDATED FINANCIAL STATEMENTS (CONTINUED)

## NOTE 10. LEASE COMMITMENTS

The Company leases its manufacturing facilities under a non-cancelable operating lease expiring in 2007 and has the option to extend this lease for one additional renewal term of five years. In January 2000, the Company entered into a seven-year lease for its corporate headquarters in Mountain View, California, which expires in January 2007.

Future minimum lease payments under operating leases are as follows (in thousands):

2001.....	\$1,247
2002.....	1,313
2003.....	1,262
2004.....	1,299
2005.....	1,348
Thereafter.....	1,517
	-----
	\$7,986
	=====

Rent expense, in thousands, under operating leases totaled \$1,235, \$994, and \$2,472 for the years ended December 31, 2000, 1999, 1998, respectively.

## NOTE 11. INCOME TAXES

Deferred income taxes result from differences in the recognition of expenses for tax and financial reporting purposes, as well as operating loss and tax credit carryforwards. Significant components of the Company's deferred income tax assets as of December 31, are as follows (in thousands):

	2000	1999
	-----	-----
Deferred tax assets:		
Net operating loss carryforwards.....	\$ 11,606	\$ 6,230
Research and development credit carryforwards.....	5,255	4,820
Capitalized research and development expenses.....	--	534
Inventory reserve.....	3,063	6,100
Accruals and other.....	4,294	5,163
Deferred gain.....	--	(272)
Depreciation.....	3,002	4,974
	-----	-----
	27,220	27,549
Valuation allowance.....	(27,220)	(27,549)
	-----	-----
Total.....	\$ --	\$ --
	=====	=====

For federal and state income tax reporting purposes, net operating loss carryforwards of approximately \$33,535 and \$5,742 are available to reduce future taxable income, if any. The federal net operating loss carryforwards expire on various dates through 2020. The state net operating loss carryforwards expire on various dates through 2010.

## NOTES TO CONSOLIDATED FINANCIAL STATEMENTS (CONTINUED)

The provision for income taxes consists of the following components for the years ended December 31, 2000 and 1999. There was no provision recorded in 1998 due to the net loss of \$80,253 reported for that year.

	2000	1999
	----	----
Current		
Federal.....	\$805	\$730
State.....	40	95
Foreign.....	10	164
	----	----
Total current provision for income taxes.....	\$855	\$989
	====	====

The provisions for income taxes differs from the amount computed by applying the statutory federal income tax rates as follows, for the years ended December 31, 2000, 1999 and 1998:

	2000	1999	1998
	----	----	----
Provision computed at federal statutory rates.....	35%	35%	(35)%
State income taxes, net of federal tax effect.....	6	6	(6)
Net operating losses utilized.....	(25)	(31)	--
Tax credits.....	(5)	--	(1)
Change in valuation allowance.....	5	--	36
Loss/(Income) not subject to federal and state taxation.....	(7)	(4)	5
Other.....	1	(1)	1
	---	---	---
Provision for income taxes.....	10%	5%	0%
	===	===	===

## NOTE 12. CONCENTRATION OF CUSTOMERS AND SUPPLIERS

Sales to significant customers as a percentage of total revenues are as follows:

	2000	1999	1998
	----	----	----
Customer A.....	18%	10%	13%
Customer B.....	17%	9%	11%
Customer C.....	15%	9%	11%
Customer D.....	10%	6%	10%
Customer E.....	10%	1%	*
Customer F.....	6%	47%	35%

- - - - -  
\* Customer's percentage did not fall in the top five

The Company did not have any suppliers making up more than 10% of operating costs.

## NOTE 13. 401(k) PLAN

All of the Company's employees are eligible to participate in the VIVUS 401(k) Plan. Employer matching contributions for the year ended December 31, 2000 were \$97 thousand. The employer matching portion of the 401(k) plan began on July 1, 2000.

## NOTE 14. LEGAL MATTERS

On November 3, 1999, the Company filed a demand for arbitration against one of its former distributors. The Company seeks compensation in the amount of \$7.9

million plus costs and interest for (i) inventory manufactured in 1998 in reliance on contractual forecasts and orders submitted; (ii) forecasts and order shortfalls pursuant to the terms of the Distribution Agreement and (iii) lost profits due to the distributor's

## NOTES TO CONSOLIDATED FINANCIAL STATEMENTS (CONTINUED)

failure to use the requisite diligence and reasonable efforts to gain regulatory approval for and launch MUSE in each country of the Territory. On October 20, 2000, this former distributor submitted its response to the Company's amended arbitration demand denying liability on all claims, and asserted counterclaims against the Company for \$1.8 million based on the Company's alleged improper calculation of its Cost of Goods charged pursuant to the Distribution Agreement. On November 20, 2000 the Company filed its response to the counterclaims, denying all liability. The Company believes that the counterclaims are without merit and intends to defend against them vigorously.

In the normal course of business, the Company receives and makes inquiries regarding patent infringement and other legal matters. The Company believes that it has meritorious claims and defenses and intends to pursue any such matters vigorously. Aside from the above matter, the Company is not aware of any asserted or unasserted claims against it where an unfavorable resolution would have an adverse material impact on the operations or financial position of the Company.

## NOTE 15. SUBSEQUENT EVENT (UNAUDITED)

In January 2001, the Company executed a development, license and supply agreement with a pharmaceutical company for its proprietary compound. Under the terms of this agreement, the Company acquired worldwide rights, except for Japan, China and certain Pacific Rim countries, to develop and commercialize the compound for oral and local treatments of male and female sexual dysfunction. During the first quarter 2001, the Company made up-front, non-refundable payments totaling \$5 million dollars to the licensor. The agreement also includes additional payments to the licensor based on certain development, regulatory and sales milestones in addition to royalties based on a percentage of net sales of products containing the compound.

ITEM 9. CHANGES IN AND DISAGREEMENTS WITH ACCOUNTANTS ON ACCOUNTING AND FINANCIAL DISCLOSURE

None.

PART III

ITEM 10. EXECUTIVE OFFICERS AND DIRECTORS OF THE REGISTRANT

The information required by this item is incorporated by reference from the discussion in the Company's Proxy Statement captioned "Proposal One: Election of Directors."

ITEM 11. EXECUTIVE COMPENSATION

The information required by this item is incorporated by reference from the discussion in the Company's Proxy Statement captioned "Executive Compensation."

ITEM 12. SECURITY OWNERSHIP OF CERTAIN BENEFICIAL OWNERS AND MANAGEMENT

The information required by this item is incorporated by reference from the discussion in the Company's Proxy Statement captioned "Record Date and Share Ownership."

ITEM 13. CERTAIN RELATIONSHIPS AND RELATED TRANSACTIONS

This information required by this item is incorporated by reference from the discussion in the Company's Proxy Statement captioned "Certain Transactions and Reports."

PART IV

ITEM 14. EXHIBITS, FINANCIAL STATEMENT SCHEDULES AND REPORTS ON FORM 8-K

(a) The following documents are filed as part of this Report:

1. FINANCIAL STATEMENTS

The financial statements of VIVUS, Inc. for the year ended December 31, 2000 together with the report of Independent Accountants, are set forth on pages 30 through 46 of this Form 10-K.

2. FINANCIAL STATEMENT SCHEDULES

Financial Statement Schedules not included in this Form 10-K have been omitted either because the information required to be set forth therein is not applicable or because the required information is shown in the consolidated financial statements or notes thereto included or incorporated by reference herein.

3. EXHIBITS

EXHIBIT NUMBER -----	DESCRIPTION -----
3.2(7)	Amended and Restated Certificate of Incorporation of the Company
3.3(4)	Bylaws of the Registrant, as amended
3.4(8)	Certificate of Designations of Rights, Preferences and Privileges of Series A Participating Preferred Stock
4.1(7)	Specimen Common Stock Certificate of the Registrant
4.2(7)	Registration Rights, as amended
4.4(1)	Form of Preferred Stock Purchase Warrant issued by the Registrant to Invemed Associates, Inc., Frazier Investment Securities, L.P., and Cristina H. Kepner

EXHIBIT NUMBER -----	DESCRIPTION -----
4.5(8)	Second Amended and Restated Preferred Shares Rights Agreement, dated as of April 15, 1997 by and between the Registrant and Harris Trust Company of California, including the Certificate of Determination, the form of Rights Certificate and the Summary of Rights attached thereto as Exhibits A, B, and C, respectively
10.1(1)+	Assignment Agreement by and between Alza Corporation and the Registrant dated December 31, 1993
10.2(1)+	Memorandum of Understanding by and between Ortho Pharmaceutical Corporation and the Registrant dated February 25, 1992
10.3(1)+	Assignment Agreement by and between Ortho Pharmaceutical Corporation and the Registrant dated June 9, 1992
10.4(1)+	License Agreement by and between Gene A. Voss, MD, Allen C. Eichler, MD, and the Registrant dated December 28, 1992
10.5A(1)+	License Agreement by and between Ortho Pharmaceutical Corporation and Kjell Holmquist AB dated June 23, 1989
10.5B(1)+	Amendment by and between Kjell Holmquist AB and the Registrant dated July 3, 1992
10.5C(1)	Amendment by and between Kjell Holmquist AB and the Registrant dated April 22, 1992
10.5D(1)+	Stock Purchase Agreement by and between Kjell Holmquist AB and the Registrant dated April 22, 1992
10.6A(1)+	License Agreement by and between Amsu, Ltd., and Ortho Pharmaceutical Corporation dated June 23, 1989
10.6B(1)+	Amendment by and between Amsu, Ltd., and the Registrant dated July 3, 1992
10.6C(1)	Amendment by and between Amsu, Ltd., and the Registrant dated April 22, 1992
10.6D(1)+	Stock Purchase Agreement by and between Amsu, Ltd., and the Registrant dated July 10, 1992
10.11(4)	Form of Indemnification Agreements by and among the Registrant and the Directors and Officers of the Registrant
10.12(2)	1991 Incentive Stock Plan and Form of Agreement, as amended
10.13(1)	1994 Director Option Plan and Form of Agreement
10.14(1)	Form of 1994 Employee Stock Purchase Plan and Form of Subscription Agreement
10.17(1)	Letter Agreement between the Registrant and Leland F. Wilson dated June 14, 1991 concerning severance pay
10.21(3)+	Distribution Services Agreement between the Registrant and Synergy Logistics, Inc. (a wholly-owned subsidiary of Cardinal Health, Inc.)+ dated February 9, 1996
10.22(3)+	Manufacturing Agreement between the Registrant and CHINOIN Pharmaceutical and Chemical Works Co., Ltd. dated December 20, 1995
10.22A(11)+	Amendment One, dated as of December 11, 1997, to the Manufacturing Agreement by and between VIVUS and CHINOIN Pharmaceutical and Chemical Works Co., Ltd. dated December 20, 1995
10.23(6)+	Distribution and Services Agreement between the Registrant and Alternate Site Distributors, Inc. dated July 17, 1996
10.24(5)+	Distribution Agreement made as of May 29, 1996 between the Registrant and ASTRAZ AB
10.24A(14)++	Amended Distribution Agreement dated December 22, 1999 between AstraZeneca and the Registrant
10.27(11)+	Distribution Agreement made as of January 22, 1997 between the Registrant and Janssen Pharmaceutica International, a division of Cilag AG International
10.27A(11)+	Amended and Restated Addendum 1091, dated as of October 29, 1997, between VIVUS International Limited and Janssen Pharmaceutica International
10.28(7)	Lease Agreement made as of January 1, 1997 between the Registrant and Airport Associates

EXHIBIT NUMBER -----	DESCRIPTION -----
10.29(7)	Lease Amendment No. 1 as of February 15, 1997 between Registrant and Airport Associates
10.29A(10)	Lease Amendment No. 2 dated July 24, 1997 by and between the Registrant and Airport Associates
10.29B(10)	Lease Amendment No. 3 dated July 24, 1997 by and between the Registrant and Airport Associates
10.31(9)+	Manufacture and Supply Agreement between Registrant and Spolana Chemical Works, A.S. dated May 30, 1997
10.32A(11)	Agreement between ADP Marshall, Inc. and the Registrant dated December 19, 1997
10.32B(11)	General Conditions of the Contract for Construction
10.32C(11)	Addendum to General Conditions of the Contract for Construction
10.34(12)+	Agreement dated as of June 30, 1998 between Registrant and Alza Corporation
10.35(12)+	Sales Force Transition Agreement dated July 6, 1998 between Registrant and Alza Corporation
10.36(13)	Form of, "Change of Control Agreements," dated July 8, 1998 by and between the Registrant and certain Executive Officers of the Company.
10.30A(13)	Amendment of lease agreement made as of October 19, 1998 by and between Registrant and 605 East Fairchild Associates, L.P.
10.37(13)	Sublease agreement made as of November 17, 1998 between Caliper Technologies, Inc. and Registrant
10.22B(13)+	Amendment Two, dated as of December 18, 1998 by and between VIVUS, Inc. and CHINOIN Pharmaceutical and Chemical Works Co.
10.31A(13)+	Amendment One, dated as of December 12, 1998 by and between VIVUS, Inc. and Spolana Chemical Works, A.S.
10.38(14)+	License Agreement by and between ASIVI, LLC, AndroSolutions, Inc., and the Registrant dated February 29, 2000
10.38A(14)+	Operating Agreement of ASIVI, LLC, between AndroSolutions, Inc. and the Registrant dated February 29, 2000
10.39(14)	Sublease agreement between KVO Public Relations, Inc. and the Registrant dated December 21, 1999
10.40(15)+	License and Supply Agreement made as of May 23, 2000 between the Registrant and Abbott Laboratories, Inc.
10.41++	License and Supply Agreement made as of November 20, 2000 between the Registrant and Paladin Labs, Inc.
10.42++	Development, License and Supply Agreement made as of January 22, 2001 between the Registrant and TANABE SEIYAKU CO., LTD.
21.2	List of Subsidiaries
23.1	Consent of Independent Public Accountants
24.1	Power of Attorney (see "Power of Attorney")

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+ Confidential treatment granted.

++ Confidential treatment requested.

- (1) Incorporated by reference to the same-numbered exhibit filed with the Registrant's Registration Statement on Form S-1 No. 33-75698, as amended.
- (2) Incorporated by reference to the same numbered exhibit filed with the Registrant's Registration Statement on Form S-1 No. 33-90390, as amended.
- (3) Incorporated by reference to the same-numbered exhibit filed with the Registrant's Annual Report on Form 10-K for the year ended December 31, 1995, as amended.
- (4) Incorporated by reference to the same numbered exhibit filed with the Registrant's Form 8-B filed with the Commission on June 24, 1996.

- (5) Incorporated by reference to the same numbered exhibit filed with the Registrant's Current Report on Form 8-K/A filed with the Commission on June 21, 1996.
- (6) Incorporated by reference to the same-numbered exhibit filed with the Registrant's Quarterly Report on Form 10-Q for the quarter ended September 30, 1996.
- (7) Incorporated by reference to the same-numbered exhibit filed with the Registrant's Annual Report on Form 10-K for the year ended December 31, 1996, as amended.
- (8) Incorporated by reference to exhibit 99.1 filed with Registrant's Amendment Number 2 to the Registration Statement of Form 8-A (File No. 0-23490) filed with the Commission on April 23, 1997.
- (9) Incorporated by reference to the same-numbered exhibit filed with the Registrant's Quarterly Report on Form 10-Q for the quarter ended June 30, 1997.
- (10) Incorporated by reference to the same numbered exhibit filed with the Registrant's Quarterly Report on Form 10-Q for the quarter ended September 30, 1997.
- (11) Incorporated by reference to the same-numbered exhibit filed with the Registrant's Annual Report on Form 10-K for the year ended December 31, 1997.
- (12) Incorporated by reference to the same-numbered exhibit filed with the Registrant's Quarterly Report on Form 10-Q for the quarter ended June 30, 1998.
- (13) Incorporated by reference to the same-numbered exhibit filed with the Registrant's Annual Report on Form 10-K for the year ended December 31, 1998.
- (14) Incorporated by reference to the same-numbered exhibit filed with the Registrant's Annual Report on Form 10-K for the year ended December 31, 1999.
- (15) Incorporated by reference to the same-numbered exhibit filed with the Registrant's Quarterly Report on Form 10-Q for the quarter ended June 30, 2000.

(b) REPORTS ON FORM 8-K

None.

## SIGNATURES

Pursuant to the requirements of Section 13 or 15(d) of the Securities Exchange Act of 1934, the Registrant has duly caused this report to be signed on its behalf by the undersigned, thereunto duly authorized:

VIVUS, INC.,  
a Delaware Corporation

By: /s/ RICHARD WALLISER

-----  
Richard Walliser  
Vice President of Finance and  
Chief Financial Officer  
(Principal Financial and Accounting  
Officer)

Date: March 26, 2001

## POWER OF ATTORNEY

KNOW ALL PERSONS BY THESE PRESENTS, that each person whose signature appears below constitutes and appoints each of Leland F. Wilson and Richard Walliser as his attorney-in-fact for him, in any and all capacities, to sign each amendment to this Report on Form 10-K, and to file the same, with exhibits thereto and other documents in connection therewith, with the Securities and Exchange Commission, hereby ratifying and confirming all that said attorney-in-fact or his substitute or substitutes may lawfully do or cause to be done by virtue hereof.

Pursuant to the requirements of the Securities Exchange Act of 1934, this Report has been signed below by the following persons on behalf of the Registrant and in the capacities and on the dates indicated:

SIGNATURE -----	TITLE -----	DATE ----
/s/ LELAND F. WILSON ----- Leland F. Wilson	President, Chief Executive Officer (Principal Executive Officer) and Director	March 26, 2001
/s/ VIRGIL A. PLACE ----- Virgil A. Place	Chairman of the Board and Chief Scientific Officer and Director	March 26, 2001
/s/ RICHARD WALLISER ----- Richard Walliser	Vice President of Finance and Chief Financial Officer (Principal Financial and Accounting Officer)	March 26, 2001
/s/ JOSEPH E. SMITH ----- Joseph E. Smith	Director	March 26, 2001
/s/ MARIO M. ROSATI ----- Mario M. Rosati	Director	March 26, 2001
/s/ MARK B. LOGAN ----- Mark B. Logan	Director	March 26, 2001
/s/ LINDA M. SHORTLIFFE, M.D. ----- Linda M. Shortliffe, M.D.	Director	March 26, 2001

## VIVUS, INC.

REPORT ON FORM 10-K FOR  
THE YEAR ENDED DECEMBER 31, 2000

## INDEX TO EXHIBITS\*

EXHIBIT NUMBER -----	EXHIBIT NAME -----	SEQUENTIALLY NUMBERED PAGE -----
10.41++	License and Supply Agreement made as of November 20, 2000 between the Registrant and Paladin Labs, Inc. ....	
10.42++	Development, License and Supply Agreement made as of January 22, 2001 between the Registrant and TANABE SEIYAKU CO., LTD. ....	
21.2	List of Subsidiaries.....	
23.1	Consent of Independent Public Accountants.....	
24.1	Power of Attorney (see "Power of Attorney").....	

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\* Only exhibits actually filed are listed. Exhibits incorporated by reference  
are set forth in the exhibit listing included in Item 14 of the Report on  
Form 10-K.

++ Confidential treatment requested.

## DISTRIBUTION AND SUPPLY AGREEMENT

This Agreement is made as of this 20th day of November, 2000, by and between Paladin Labs Inc., 6111 Royalmount Avenue, Suite 102, Montreal, Quebec, Canada H4P 2T4 ("Paladin") and VIVUS International, Ltd., a company organized under the laws of Bermuda, with its principal offices at Clarendon House, Church Street, Hamilton, Bermuda. ("VIVUS").

## RECITALS

WHEREAS, VIVUS has developed MUSE(R), a non-injectable product for the treatment of erectile dysfunction consisting of a microsuppository of alprostadil for local delivery to the male urethra; and

WHEREAS, Paladin is interested in obtaining a license relating to such product; and VIVUS is interested in granting such license to Paladin; and

NOW, THEREFORE, in consideration of the mutual obligations and promises as set forth herein, the parties do hereby agree as follows:

## ARTICLE 1 - DEFINITIONS

For purposes of this Agreement, the following terms shall have the following respective meanings:

- 1.1 Affiliate means any corporation, firm, partnership or other entity, whether de jure or de facto, that directly or indirectly owns, is owned by or is under common ownership with a party to the extent of in excess of fifty percent (50%) of the outstanding securities or assets having the power to vote on or direct the affairs of the entity.
- 1.2 Confidential Information means any information, data or business plans relating to the Product or otherwise to the subject of this Agreement, which a party discloses to the other party, except any portion thereof which:
  - (i) is known to the receiving party at the time of disclosure and documented by written records made prior to the date of this Agreement;
  - (ii) is disclosed to the receiving party by a third person who has a right to make such disclosure;
  - (iii) becomes patented, published or otherwise part of the public domain through no fault of the receiving party; or
  - (iv) is independently developed by the receiving party as evidenced by its written records.
- 1.3 Effective Date means the date of this Agreement first written above.

- 1.4 First Commercial Sale means the first sale of Product (as defined below) in the Territory by Paladin or any Paladin Affiliate or sublicensee to any unaffiliated third party.
- 1.5 Patents means all patents and patent applications (including without limitation, continuations, continuations-in-part, divisionals, patents of addition, substitutions, extensions, reissues, re-examinations, renewals, or SPCs), owned by or licensed (with the right to sublicense) to VIVUS or VIVUS, INC. or its or their Affiliates during the term of this Agreement, and generically or specifically claiming a Product, a process for manufacturing a Product, an intermediate used in such process, or a use of a Product. With respect to such patents or applications that VIVUS or VIVUS INC. or its or their Affiliates licenses or acquires or has licensed or acquired from a third party, the same shall be included within "Patents" hereunder to the extent that VIVUS or VIVUS INC. or its or their Affiliates has the right to license or sublicense the same hereunder. A list of current and applicable Patents is attached as Exhibit 1.5.
- 1.6 Marketing Authorization means all governmental approvals and authorizations necessary for the commercial marketing and sale of the Product in the Territory, excluding any pricing approval and pricing reimbursement.
- 1.7 Net Sales means the gross sales of the Product shipped by Paladin and/or its Affiliates or sub licensee to third parties in the Territory (as defined below) less deductions allowed to the final buyer against invoiced amounts for:
- a. trade discounts earned or granted;
  - b. cash discounts actually allowed;
  - c. transportation charges (including insurance costs), handling charges, sales taxes, excise, turnover, inventory, value added and similar taxes, duties and charges invoiced to customers;
  - d. retroactive price reductions imposed by government authorities;
  - e. wholesaler charge backs earned or granted;
  - f. rebates and management fees earned by or granted to third parties; and
  - g. actual bad debts incurred to a maximum of one-half of one percent (.05%) of Net Sales in any Sales Year.
- 1.8 Product means (1) the product for the transurethral delivery of alprostadil and which VIVUS and/or VIVUS INC. sells outside the Territory, as of the Effective Date, under the trademark MUSE ("Product") and (2) any and all improvements to the Product which are sold under the MUSE trademark outside the Territory.

- 1.9 Regulatory Approval means all governmental approvals and authorizations necessary for the commercial sale of the Product in a country in the Territory, including but not limited to Marketing Authorization, pricing approval and pricing reimbursement.
- 1.10 Sales Quarter means for the first Quarter, the period commencing on the date of Paladin's First Commercial Sale and ending on the last day of that calendar quarter; and for subsequent Sales Quarters, the successive calendar quarters thereafter.
- 1.11 Sales Year means for the first Sales Year, the period commencing on the date of Paladin's First Commercial Sale and ending on December 31st of that year; and for subsequent Sales Years, the successive calendar years thereafter.
- 1.12 Specifications means the manufacturing release specifications and stability specifications for the Product in the Territory.
- 1.13 SPC means a right based upon a Licensed Patent to exclude others from making, using or selling a Product, such as a Supplementary Protection Certificate.
- 1.14 Supply Price means the price as set forth in Article 4.2 below.
- 1.15 Trademark means the trademark MUSE. The MUSE(R) Trademark is registered or has pending registration applications in the Territory as of the Effective Date.
- 1.16 Territory means Canada.

#### ARTICLE 2 - GRANT OF RIGHTS

- 2.1 Appointment. VIVUS hereby grants to Paladin an exclusive license (exclusive even as to VIVUS) to use and sell the Product in the Territory. Paladin may sublicense any one or more of its Affiliates at Paladin's sole discretion, and may sublicense third parties with VIVUS's prior written consent, such consent not to be unreasonably withheld. This exclusive license is granted to Paladin as to all uses, forms, indications, packages and strengths for the Product.

#### ARTICLE 3 - LICENSE FEES

- 3.1 Subject to Articles 9.2 and 9.3, Paladin shall pay VIVUS the following one-time, non-creditable and non-cumulative license fees within thirty (30) days after the event specified:
- a. (\*\*), upon the first occasion on which Paladin achieves annual Net Sales of the Product in a Sales Year of (\*\*) in the Territory; and
  - b. (\*\*), upon the first occasion on which Paladin achieves annual Net Sales of the Product in a Sales Year of (\*\*) in the Territory.

## ARTICLE 4 - PURCHASE AND SALE

- 4.1 Purchases and Sale of Product. Subject to the terms and conditions of this Agreement, VIVUS shall sell Product exclusively to Paladin in the Territory and Paladin shall purchase its requirements of Product exclusively from VIVUS, at the Supply Price.
- 4.2 Supply Price. Subject to Article 4.3, the Supply Price shall equal (\*\*\*) of Paladin's Net Sales of the Product in the Territory, calculated as provided in Article 4.2(b) below.
- a. In order to enable the parties to sell and purchase the Product prior to the time in which Paladin's Net Sales for a Sales Quarter are determined, Paladin shall pay for Product ordered, delivered and accepted pursuant to Article 5 below based upon an interim "Transfer Price," which shall be equal to (\*\*\*) of Paladin's estimated average net selling price per unit for the Product in the Territory. Paladin shall advise VIVUS no later than forty-five (45) days prior to the start of each Sales Year during the term of this Agreement of Paladin's estimated average net selling price per unit of Product in the Territory for the coming Sales Year, and the Transfer Price for that Sales Year shall be based upon such price, subject to any adjustment required under Article 4.2(b) below.
- b. The parties shall conduct a reconciliation no later than forty-five (45) days after the end of each Sales Quarter, in order to determine whether one party owes the other party any amount in connection with the sale and purchase of the Product in that Sales Quarter, based upon the difference (if any) between the respective Transfer Price and the Supply Price for that Sales Quarter. For the purposes of such reconciliation, Paladin shall provide to VIVUS a statement of Paladin's sales in units in the Territory, and of Paladin's Net Sales in the Territory and in local currency as well as in U.S. dollars, converted pursuant to Article 4.6 below. In the event that one party owes the other party any amount in accordance with this Article 4.2(b), the owing party shall pay such amount within thirty (30) days of the date upon which the parties have agreed in writing upon the reconciliation calculation. In the event that the Supply Price is greater than one hundred ten percent (110%) or less than ninety percent (90%) of the Transfer Price for two (2) consecutive Sales Quarters, the Transfer Price established in Article 4.2(a) above shall be changed for the remainder of that Sales Year to the Supply Price applicable to the most recent Sales Quarter.
- 4.3 Minimum Supply Price. Starting after the first Sales Year, the Supply Price for the Product shall in no event be less than the Minimum Supply Price as set forth in Exhibit 4 attached to this Agreement.

- 4.4 Samples. VIVUS shall sell a quantity of Product to Paladin for use as samples, at "Sample Prices" as set forth in Exhibit 4 attached to this Agreement. Paladin may purchase such samples in quantities not to exceed the following percentages of Paladin's total unit purchases of Product in the Territory:
- a. Ten percent (10%) in each of the first two (2) Sales Years;
  - b. Seven percent (7%) in each of the third and fourth Sales Years; and
  - c. Five percent (5%) in each Sales Year thereafter.
- 4.5 Records. Paladin and/or its Affiliates shall keep and maintain records of sales made pursuant to the license granted hereunder so that Paladin's Net Sales and the calculation of the Transfer Price and the Supply Price may be verified. Such records shall be open to inspection upon prior written notice at any reasonable time during business hours, not more than once per calendar year, and each inspection shall cover no more than the two (2) calendar years preceding such notice of inspection. The inspection shall be conducted at VIVUS's expense by a nationally recognized independent certified public accountant who is not VIVUS's auditor of record and who is selected by VIVUS and approved by Paladin, which approval shall not be unreasonably withheld, and shall then have the right to examine the records kept pursuant to this Agreement and report to VIVUS the findings (but not the underlying data) of the inspection as are necessary to evidence that the records were or were not maintained and used in accordance with this Agreement. A copy of any report provided to VIVUS by the accountant shall be given concurrently to Paladin. If the inspection of records reveals more than five percent (5%) underpayment by Paladin for the purchase of the Product (calculated as a percentage of all such payments made in connection with a Sales Year), then the expenses for the accountant shall be borne by Paladin and Paladin shall promptly repay to VIVUS the amount of such underpayment, plus interest calculated at the U.S. prime rate of interest as published in the Wall Street Journal for the date upon which such underpayment was made. For the purposes of this Article 4.5, an "underpayment" shall not include any amount that the parties determine is owed to VIVUS pursuant to the reconciliation procedure set forth in Article 4.2(b) above. If the inspection of records reveals an overpayment by Paladin for the purchase of the Product (calculated as a percentage of all such payments made in connection with a Sales Year), then the expenses for the accountant shall be borne by VIVUS and VIVUS shall promptly repay to Paladin the amount of such overpayment.

- 4.6 Payments. Any payments due VIVUS or Paladin under this Agreement shall be made by remitting to the bank account designated by the party to whom payment is to be made. Any such payments shall be made in U.S. Dollars and, in the case of quarterly payments based upon Paladin Net Sales in currencies other than U.S. Dollars, such quarterly payments shall be the sum of payments due for the three (3) months of the applicable quarter calculated for each such month using the beginning and ending month's published exchange rate, set one business day prior to month end, by Reuters divided by two (if a Reuters exchange rate is not available, an exchange rate established by a recognized third party will be used.) Any payment which is more than ten (10) days overdue shall bear interest from the original due date at the U.S. prime rate of interest as published in the Wall Street Journal for the due date.
- 4.7 Taxes. Where any sum due to be paid to VIVUS hereunder is subject to any withholding or similar tax, the parties shall use their best efforts to do all such acts and things and to sign all such documents as will enable them to take advantage of any applicable double taxation agreement or treaty. In the event there is no applicable double taxation agreement or treaty, or if an applicable double taxation agreement or treaty reduces but does not eliminate such withholding or similar tax, Paladin shall pay such withholding or similar tax to the appropriate government authority, deduct the amount paid from the amount due VIVUS and secure and send to VIVUS the best available evidence of such payment.

#### ARTICLE 5 - FORECASTS, ORDERS, INVOICES AND TITLE

- 5.1 Initial Forecast. Within thirty (30) days of the Effective Date, Paladin shall give VIVUS its then current best forecast of the quantity of Product that Paladin will require from VIVUS prior to and during the first four Sales Quarters. Paladin shall break down the forecast for the period prior to the first Sales Quarter and for the first two Sales Quarters of such forecast by month and by Stock Keeping Unit ("SKU") per Product.
- 5.2 Rolling Forecasts. No later than ninety (90) days prior to the first day of each Sales Quarter after the initial Sales Quarter, Paladin shall give VIVUS its then current best forecast of the quantity of Product that Paladin will require from VIVUS during each of the next four (4) Sales Quarters. Paladin shall break down the forecast for the first two such Sales Quarters of the forecast by month and by SKU per Product.

- 5.3 Order and Acceptance. The forecast for the first Sales Quarter in each of Paladin's rolling forecasts made pursuant to Article 5.2 above shall constitute Paladin's firm order for that Sales Quarter, and all firm orders shall specify delivery date(s) no less than ninety (90) days from the date of such firm order. Paladin shall not increase or decrease its forecast (by SKU and in total), for the second Sales Quarter in each of Paladin's rolling forecasts made pursuant to Article 5.2 above, by more than twenty percent (20%). VIVUS shall accept all firm orders from Paladin for quantities of Product up to and including one hundred twenty percent (120%) of the quantity (by SKU and in total) of Product previously forecasted by Paladin for such Sales Quarter, and shall use its best efforts to accept all firm orders from Paladin for quantities of Product in excess of that quantity of Product. Paladin shall not increase or decrease its forecast, for the third Sales Quarter in each of Paladin's rolling forecasts made pursuant to Article 5.2 above, by more than fifty percent (50%). VIVUS shall accept all firm orders from Paladin for quantities of Product up to and including one hundred fifty percent (150%) of the quantity of Product previously forecasted by Paladin for such Sales Quarter, and shall use its best efforts to accept all firm orders from Paladin for quantities of Product in excess of that quantity of Product. Once an order has been accepted by VIVUS, then VIVUS shall be obligated to sell, and Paladin shall be obligated to purchase, the ordered Product. It is understood and agreed that VIVUS' obligations to supply Product will be in full lot quantities and that VIVUS will not split lots for supply of Product to Paladin in the Territory.
- 5.4 Invoices. VIVUS shall invoice Paladin for the Transfer Price in United States dollars for the Product shipped on the day of shipment. Paladin shall pay VIVUS such invoiced amount within thirty (30) days from the date of the receipt of the Product.
- 5.5 Delivery. VIVUS shall deliver the Product to Paladin, FOB at VIVUS's facilities located in Lakewood, New Jersey, USA. All shipping costs, liability, ownership and logistics of Product beyond the Lakewood facility's loading dock are the responsibility of Paladin.
- 5.6 Conflicting Terms and Conditions. Except as otherwise provided in this Agreement, the terms and conditions of this Agreement shall govern, notwithstanding any additional or inconsistent terms or conditions in Paladin's form of purchase order or similar document or in VIVUS's acknowledgment, invoice, or similar documents.

#### ARTICLE 6 - SAMPLING, TESTING AND ANALYSIS

- 6.1 Certificate of Analysis. VIVUS shall test or cause to be tested each lot of the Product pursuant to the Specifications before delivery to Paladin. Each test shall set forth the items tested, specifications and test results in a certificate of analysis for each lot delivered. VIVUS shall send or cause to be sent such certificates to Paladin along with delivery of the Product. Paladin is entitled to rely on such certificates for all purposes of this Agreement. Paladin will perform, at its own expense, any testing upon entry of the Product into the Territory that is necessary for the sale or distribution of such Product in the Territory.

- 6.2 Defective Product. Paladin shall notify VIVUS in writing of any claim relating to damaged, defective or nonconforming Product or any shortage in quantity of any shipment of the Product within thirty (30) days of receipt of such Product or, if the defect is not readily apparent based upon a reasonable inspection (a "Hidden Defect"), within thirty (30) days after which the Hidden Defect becomes known to Paladin. A Hidden Defect is defined as a defect that existed at the time Product is delivered and, for avoidance of doubt, a Hidden Defect does not include any defect that might be caused in storage or transportation of the Product. If Paladin fails to give such written claim notice to VIVUS within said thirty (30) day period, the Product shipped shall be deemed to be conforming, not damaged nor defective at the time of delivery and shall be deemed to be sufficient in quantity. If Paladin gives such written claim notice to VIVUS within said thirty (30) day period, then Paladin and VIVUS shall, in an appropriate manner to be agreed, jointly inspect the Product to see if claimed nonconformity, damage or defect actually exists in the Product shipped. If existence of claimed nonconformity, damage, defect or shortage is reasonably verified through such inspection, VIVUS shall replace the rejected Product or make up the shortage as soon as practicable but no later than ninety (90) days after such verification, at no extra cost to Paladin, and shall make arrangements with Paladin for the destruction of any rejected Product, at VIVUS's expense.
- 6.3 Specifications. The Specifications may be modified in accordance with regulatory requirements by written agreement of the parties without the necessity of amending this Agreement.
- 6.4 Technical Agreement. Within ninety (90) days of the Effective Date, VIVUS and Paladin shall enter into a separate technical agreement, in a format suitable for submission to the regulatory authorities in the Territory, recording the Specifications and Manufacturing Standards and measures to ensure compliance with applicable regulations relating to production, storage, transportation and release of the Product.

#### ARTICLE 7 - PATENTS

- 7.1 Patent Prosecution and Maintenance. To the extent it has the right to do so, VIVUS shall, at its sole cost and expense, maintain any patent applications and patents and shall diligently prosecute any such patent applications and obtain all available patent term extensions in the Territory; provided that VIVUS may decide not to prosecute certain Patents, or to cause or permit certain of the Patents to lapse or become abandoned in the Territory if, in VIVUS's reasonable commercial judgment, such decision would not adversely affect Paladin's ability to exercise its rights and perform its obligations under this Agreement.

## ARTICLE 8 - DEVELOPMENT AND REGULATORY ISSUES

- 8.1 VIVUS Responsibilities. VIVUS shall be responsible for, and shall bear all costs of the following:
- a. Promptly after the Effective Date, VIVUS shall arrange for the transfer to Paladin of all Marketing Authorizations in the Territory for the Product as expeditiously as possible.
  - b. VIVUS shall provide to Paladin, as expeditiously as possible, appropriate assistance, information and/or materials in VIVUS's possession or control in order to enable or facilitate Paladin to market and sell the Product in the Territory.
  - c. In fulfilling its obligations under this Agreement, VIVUS shall use its best efforts to ensure that the Product is entitled to and receives the maximum available benefit of any regulatory market exclusivity periods or other safeguards or extensions of proprietary status, which are or may be applicable in the Territory.
  - d. VIVUS shall be responsible for filing trademark applications for, and for the maintenance and upkeep of, the Trademark in the Territory.
- 8.2 Paladin Responsibilities. During the term of this Agreement, Paladin shall be responsible for, and shall bear all cost of, the following:
- a. Paladin shall, at its own expense, be responsible for
    - (i) maintaining all Marketing Authorizations for the Product in the Territory;
    - (ii) obtaining all pricing and reimbursement approvals in Paladin's name for the Product in the Territory; and
    - (iii) obtaining and maintaining all Regulatory Approvals in Paladin's name.
  - b. Paladin shall own all registrations and Regulatory Approvals for the Product in the Territory.
  - c. In fulfilling its obligations under this Agreement, Paladin shall use its best efforts to ensure that the Product is entitled to and receives the maximum available benefit of any regulatory market exclusivity periods or other safeguards or extensions of proprietary status, which are or may be applicable in the Territory.

- 8.3 Pharmacovigilance. Promptly after the Effective Date and prior to Product distribution by Paladin, the respective pharmacovigilance groups of VIVUS and Paladin shall enter into a separate agreement covering adverse event information exchange relating to the Product. Such agreement will permit the inclusion of the respective pharmacovigilance groups of other third parties to whom VIVUS has granted or will grant (during the term of this Agreement) a license under the VIVUS Technology to make, have made, use and sell the Product outside the Territory.
- 8.4 Regulatory Communications. Paladin and VIVUS shall promptly inform each other of any material communications to or from governmental authorities or agencies relating to the Product that affect marketing and/or sale of Product in the Territory. With the exception of product recalls, which are to be handled pursuant to Article 10 below, and adverse event reporting, which is to be handled pursuant to Article 8.3 above, the parties shall consult with each other regarding any issues raised in such communications, and shall attempt in good faith to agree upon any action to be taken or response to be made in connection with such communications. If the parties are unable to agree within a reasonable time prior to when the action is to be taken or the response is to be made the party receiving the material communication for the Product shall decide what action to take or response to make.
- 8.5 Expiration Dating. The Product has approved expiration dating of twenty-four (24) months in the Territory as of the Effective Date of this Agreement. At Paladin's request, VIVUS shall cooperate with and provide all reasonable assistance, including providing appropriate supporting stability data, if any, to extend the expiration date for the Product in the Territory beyond twenty-four (24) months. Paladin shall bear all costs associated with gaining regulatory approval for such an extension.

#### ARTICLE 9 - MARKETING AND SALES

- 9.1 Paladin Diligence. In addition to the items set forth in Article 3.1 above, Paladin shall use its diligent efforts to market and/or sell the Product in the Territory, consistent with the efforts that Paladin expends on pursuing commercialization of other products Paladin markets in the Territory of similar market potential, including but not limited to product for the treatment of erectile dysfunction, taking into consideration the proprietary or non-proprietary status of the Product.
- 9.2 License Fees. In the event that the license fee provided in Article 3.1(a) above does not become payable by the end of the fourth Sales Year, or that the license fee provided in Article 3.1(b) above does not become payable by the end of the sixth Sales Year, then VIVUS may terminate this Agreement upon thirty (30) days written notice; provided that in either event, Paladin may, at its option, avoid termination by paying to VIVUS an amount equal to the license fee otherwise applicable under Article 3.1(a) or (b) (as the case may be). If Paladin makes such payment within thirty (30) days of the date of VIVUS's notice of termination, then such notice shall become null and void, and this Agreement shall remain in full force and effect.

9.3 Adjustment to License Fee. The license fee payment contemplated in Article 3.1 (a) and Article 3.1 (b) shall be adjusted according to the following schedule in the event that Paladin's gross margin falls below (\*\*\*) during the twelve (12) month period prior to the license fee being payable to VIVUS in Article 9.2. Gross Margin shall be defined as Net Sales less the Supply Price actually paid pursuant to Articles 4.2 and 4.3 above.

Adjustment Schedule to License Fee

Gross Margin	Adjusted License Fee
(***)	(***) as per Articles 3.1(a) & (b)
(***)	(***)
(***)	(***)
(***)	(***)
(***)	(***)

ARTICLE 10 - PRODUCT RECALL

10.1 Recall in the Territory. In the event that in the Territory (i) any government authority issues a request, directive or order that the Product be recalled, or (ii) a court of competent jurisdiction orders such a recall, or (iii) Paladin and VIVUS jointly determine that the Product should be recalled, Paladin shall take all appropriate corrective actions. If such recall results from any cause or event attributable solely to VIVUS's negligence or fault, VIVUS shall be responsible for the direct expenses of the recall. If such recall results from any cause or event attributable solely to Paladin's negligence or fault, Paladin shall be responsible for the direct expenses of the recall. If such recall results from any other cause or event (including attribution to the negligence or fault of both VIVUS and Paladin), the parties shall share equally the direct expenses of the recall. For the purposes of this Agreement, the direct expenses of recall shall include, without limitation, the expenses of notification and return of the recalled Product and Paladin's costs for the Product, and shall not include the cost of any re-launch by Paladin of the Product in the Territory subsequent to a recall.

10.2 Recall Outside the Territory. In the event that outside the Territory (i) any government authority issues a request, directive or order that the Product be recalled, or (ii) a court of competent jurisdiction orders such a recall, or (iii) VIVUS (or its Affiliates or sublicensees, as the case may be) decides that the Product should be recalled, VIVUS shall notify Paladin as expeditiously as possible and shall provide Paladin with all information and assistance as Paladin may reasonably request in order to enable Paladin to determine any appropriate actions relating to the Product in the Territory arising from such recall.

## ARTICLE 11 - REPRESENTATIONS AND WARRANTIES

Each party hereby represents and warrants for itself as follows:

- 11.1 Organized. It is a corporation duly organized, validly existing and is in good standing under the laws of the jurisdiction of its incorporation, is qualified to do business and is in good standing as a foreign corporation in each jurisdiction in which the conduct of its business or the ownership of its properties requires such qualification and failure to have such would prevent it from performing its obligations under this Agreement and has all requisite corporate power and authority to conduct its business as now being conducted, to own, lease and operate its properties and to execute, deliver and perform this Agreement.
- 11.2 Due Execution. The execution, delivery and performance by it of this Agreement have been duly authorized by all necessary corporate action and do not and will not (i) require any consent or approval of its stockholders; (ii) violate any provision of any law, rule, regulation, order, writ, judgment, injunction, decree, determination or award presently in effect having applicability to it or any provision of its charter or by-laws; or (iii) result in a breach of or constitute a default under any material agreement, mortgage, lease, license (including any license from a third party which is necessary for the full performance of this Agreement), permit or other instrument or obligation to which it is a party or by which it or its properties may be bound or affected.
- 11.3 No Third Party Approval. No authorization, consent, approval, license, exemption of, or filing or registration with, any court or governmental authority or regulatory body (other than health regulatory authorities) is required for the due execution, delivery or performance by it of this Agreement, except as provided herein.
- 11.4 Binding Agreement. This Agreement is a legal, valid and binding obligation of such party, enforceable against it in accordance with its terms and conditions. It is not under any obligation to any person, contractual or otherwise, that is in conflict with the terms of this Agreement.
- 11.5 Full Disclosure. Each Party has disclosed to the other in good faith all material information relevant to the subject matter of this Agreement and to such party's ability to observe and perform its obligations hereunder.

## ARTICLE 12 - COVENANTS, REPRESENTATIONS AND WARRANTIES OF VIVUS

VIVUS covenants, represents and warrants to Paladin that:

- 12.1 VIVUS Rights. VIVUS has the right to grant the rights granted in this Agreement and no provision in any third party agreement to which VIVUS is a party will prevent VIVUS from performing its obligations under this Agreement.

- 12.2 Specifications. All quantities of the Product will comply with, and VIVUS shall only release Product for shipment to Paladin which comply with (i) all specifications of the Product in the Marketing Authorization applications approved by the regulatory authorities in the Territory; (ii) all Specifications; and (iii) all applicable legal and regulatory requirements relating to the manufacture of the Product for sale in the Territory, including but not limited to Good Manufacturing Practices.
- 12.3 Quality of Starting Materials and Packing Materials. All starting materials and packaging materials used in the manufacture of the Product shall comply with the applicable Specifications and the Manufacturing Standards (as defined below).
- 12.4 Current Good Manufacturing Practices ("cGMP")/Regulatory Requirements. All manufacturing and quality control methods utilized by VIVUS in the manufacture of the Product shall be carried out and in accordance with all applicable rules governing medicinal product and/or medical devices in the Good Manufacturing Practice for medicinal product and/or medical devices and regulations issued by the health regulatory authorities in the Territory for which such Product is to be sold as in effect at the time and the applicable standards in effect at the time (collectively, the "Manufacturing Standards").
- 12.5 Documentation. VIVUS shall keep and maintain, for the approved shelf life of the Product plus two (2) years, (i) reference samples and quality control records for each batch of starting materials and packaging material used in the manufacture of the Product, and (ii) manufacturing and quality control records for each batch of the Product. Each shipment of the Product shall be accompanied by the following written documentation:
- a. the date of manufacture;
  - b. delivered amount of Product units; and
  - c. a certificate of analysis pursuant to Article 6.
- 12.6 Paladin Right of Inspection. VIVUS shall, upon written request of Paladin, permit Paladin's authorized third-party representative to inspect the following records related to Product manufactured for sale by Paladin in the Territory: (i) all manufacturing and quality control records for all manufacture of the Product, and (ii) quality control records of all starting materials used in the manufacture of each of the Product. Such inspection to take place at VIVUS's facilities in Lakewood, New Jersey, during normal business hours.
- 12.7 Shelf Life. At the time of delivery to Paladin, each lot of the Product delivered pursuant to this Agreement shall be no more than five (5) months past its manufacturing date. Notwithstanding the above, Paladin shall be under no obligation to purchase Product that has, on receipt at Paladin, under 18 months of shelf life remaining.

- 12.8 Product Liability Insurance. The Parties shall maintain product liability insurance consistent with their normal business practices from time to time to cover risks related to the Product and, upon either Party's request, to provide the other Party with certificates of insurance attesting to the existence of such insurance.
- 12.9 Coverage. During the Term and for a period of two (2) years thereafter, each Party shall obtain and maintain insurance coverage from a reputable arm's-length insurer in respect of its respective obligations under Article 12.8 and in respect of third-Person liability in an amount of not less than Three Million United States Dollars (\$3,000,000). Each Party shall add the other Party as a co-insured under its respective insurance policy.

#### ARTICLE 13 - FORCE MAJEURE

Upon occurrence of an event of force majeure, the party affected shall promptly notify the other party in writing, setting forth the details of the occurrence, its expected duration and how that party's performance of its obligations under this Agreement is affected. The affected party shall resume the performance of its obligations as soon as practicable after the force majeure event ceases. If a party's performance of any obligation under this Agreement is significantly hindered or is prevented by an event of force majeure for more than six (6) months, whether or not consecutive, in any twelve (12) month period, then the other party may terminate this Agreement upon thirty (30) days' notice.

#### ARTICLE 14 - ALLOCATION OF SUPPLY

- 14.1 Allocation of Supply. In the event of VIVUS's inability to supply the Product ordered by Paladin, VIVUS shall allocate its available supply between Paladin, VIVUS and VIVUS's licensee(s) outside the Territory on a fair and equitable basis based on a pro-rata share of worldwide Product sales for the six (6) months preceding and the forecasted worldwide Product sales for the next six (6) months following such allocation. SUCH ALLOCATION SHALL BE PALADIN'S SOLE REMEDY FOR VIVUS'S FAILURE TO SUPPLY PALADIN QUANTITIES OF PRODUCT VIVUS IS OTHERWISE OBLIGATED TO SUPPLY UNDER ARTICLE 5 OF THIS AGREEMENT.

#### ARTICLE 15 - TRADEMARKS

- 15.1 Trademark Rights. VIVUS hereby grants to Paladin the exclusive right, exclusive even as to VIVUS, to use the Trademarks in connection with the Product in the Territory during the term of this Agreement. Paladin acknowledges that such Trademarks shall be and are the sole property of VIVUS.
- 15.2 Electronic Address. VIVUS hereby grants to Paladin a non-exclusive right to use VIVUS's registered electronic address, [www.vivus.com](http://www.vivus.com), for the purpose of linking electronic users with Paladin's relevant web pages, web sites or other electronic addresses relating to the Product in the Territory. Paladin hereby grants to VIVUS a non-exclusive right to use Paladin's registered electronic address, [www.paladin-labs.com](http://www.paladin-labs.com), for the purpose of linking electronic users with VIVUS's relevant web pages, web sites or other electronic addresses relating to the Product.

## ARTICLE 16 - INFRINGEMENT

- 16.1 Third Party Infringement. Each party will notify the other party if it becomes aware of the activities of any third party that are believed to infringe any of the Patents or Trademarks. The parties shall consult as to potential strategies against the alleged infringer, including but not limited to litigation strategy.
- 16.2 Litigation.
- a. If the efforts of the parties are not successful in abating the alleged infringement, then VIVUS shall have the right, but not the obligation, to bring an appropriate suit or action against such infringement, at its own expense. Paladin agrees to cooperate in any such infringement action and agrees to execute all papers and perform such other acts as may be reasonably requested by VIVUS at Paladin's expense. VIVUS shall consult with Paladin and take into account Paladin's recommendations regarding the conduct of such action, provided that VIVUS shall have full right and authority to determine the strategy and tactics for such action and to settle, consent to judgment, or otherwise resolve any such action or suit. The provisions of the foregoing notwithstanding, no such resolution shall be binding on Paladin without its prior written consent (which consent shall not be unreasonably withheld) unless such resolution does not (i) impose any liability, loss, cost or obligation upon Paladin and (ii) adversely affect Paladin's rights under this Agreement.
  - b. If VIVUS does not elect to bring suit against the alleged infringer, Paladin shall have the right, but not the obligation, to bring an appropriate suit or action against such infringer in the Territory, at Paladin's own expense. VIVUS agrees to cooperate in any such infringement action and agrees to execute all papers and perform such other acts as may be reasonably requested by Paladin (including but not limited to consent to be joined as a nominal party plaintiff in such action), at VIVUS's expense. Paladin shall consult with VIVUS and take into account VIVUS's recommendations regarding the conduct of such action, provided that Paladin shall have full right and authority to determine the strategy and tactics for such action and to settle, consent to judgment, or otherwise resolve any such action or suit. The provisions of the foregoing notwithstanding, no such resolution shall be binding on VIVUS without its prior written consent (which consent shall not be unreasonably withheld) unless such resolution does not (i) impose any liability, loss, cost or obligation upon VIVUS and (ii) adversely affect VIVUS's rights under this Agreement.
  - c. If VIVUS or Paladin brings an infringement action pursuant to this Article 16, any amount recovered in any action or suit against a third party infringer shall be allocated as follows: first, to the party bringing such action in order to reimburse such party for the costs and expenses of such action; second, with respect to any remaining amount, (\*\*\*) of that portion of such amount resulting from

infringement within the Territory to Paladin, and the rest of any remaining amount to VIVUS.

## ARTICLE 17 - TERM AND TERMINATION

- 17.1 Term. The term of this Agreement shall commence on the Effective Date and shall, unless earlier terminated pursuant to this Article 17 or other express termination provisions in this Agreement, expire on the tenth (10th) anniversary of the First Commercial Sale of Product.
- 17.2 Breach. Either party may, in addition to any other remedies available to it by law or in equity, terminate this Agreement upon sixty (60) days' written notice in the event that the other party commits a material breach of this Agreement and fails to cure such breach within sixty (60) days of notice of the breach. The party giving notice of breach may withhold any payments otherwise due and owing to the breaching party, to be used as a setoff against any loss or damage arising from the breach, and said withholding shall not constitute breach of this Agreement. Any amounts so withheld shall be deposited by the withholding party into an interest-bearing escrow account. If the breaching party cures the breach within the sixty (60) day cure period and this Agreement is not terminated, then the withholding party shall promptly pay to the other party the withheld amount, less that portion of such amount which was applied as a setoff. Notwithstanding the foregoing provision, if Paladin gives notice of breach to VIVUS, Paladin may withhold other payments pursuant to this Article 17.2 but shall not be entitled to withhold payment for Product actually ordered by and delivered to Paladin pursuant to Article 5 of this Agreement.
- 17.3 Insolvency or Bankruptcy. Either party may, in addition to any other remedies available to it by law or in equity, terminate this Agreement, upon thirty (30) days' written notice to the other party in the event the other party shall have become insolvent or bankrupt, or shall have made an assignment for the benefit of its creditors, or there shall have been appointed a trustee or receiver of the other party or for all or a substantial part of its property, or any case or proceeding shall have been commenced or other action taken by or against the other party in bankruptcy or seeking reorganization, liquidation, dissolution, winding-up, arrangement, composition or readjustment of its debts or any relief under any bankruptcy, insolvency, reorganization or other similar act or law of any jurisdiction now or hereinafter in effect.
- 17.4 Serious Events. Should there occur serious and unexpected events which, from a reasonable pharmaceutical company's point of view, would make it impossible or impracticable to pursue the commercialization of the Product, including but not limited to a serious adverse event associated with the Product, either party may, with full consultation with the other party, terminate this Agreement upon thirty (30) days' written notice. Termination by a party in good faith pursuant to this Article 17.4 shall not, in itself, constitute a basis for any claim for compensation or other remedies by the other party. In the event of termination by VIVUS under this Article 17.4, VIVUS shall be restricted from commercializing the Product, either directly or indirectly, for a period of two (2) years in the Territory.

- 17.5 Change of Control or Ownership. Either party may terminate this Agreement upon thirty (30) days' written notice if the ownership or control of at least fifty percent (50%) of the assets or voting securities of the other party are transferred and, in the non-changing party's reasonable judgment, the other party's new owner or controlling entity is a competitor of the non-changing party in the field of erectile dysfunction in the Territory.
- 17.6 Survival of Liability. Except as expressly provided otherwise in this Agreement, termination, expiration, cancellation or abandonment of this Agreement through any means and for any reason shall not relieve the parties of any obligation accruing prior thereto and shall be without prejudice to the rights and remedies of either party with respect to any antecedent breach of any provision of this Agreement.
- 17.7 Remaining Inventory. Paladin shall maintain a normal level of inventory of the Product prior to expiration or termination of this Agreement, and shall have a period of six (6) months from the date of termination of this Agreement during which it may sell its remaining inventory of Product, provided it sell such inventory in a manner substantially similar to the manner in which it was selling Product prior to the termination.
- 17.8 Survival. Upon expiration or termination of this Agreement, all rights and obligations of the parties under this Agreement shall terminate except those rights and obligations described in Articles 1, 4.5, 10.1, 12.5, 17, 18, 19 and 20.

#### ARTICLE 18 - INDEMNITY

- 18.1 Indemnification by Paladin. Paladin shall defend, indemnify and hold harmless VIVUS, its officers, directors, shareholders, employees, successor and assigns from any loss, damage, or liability, including reasonable attorney's fees, resulting from any claim, complaint, suit, proceeding or cause of action by a Third Party against any of them alleging physical injury or death or otherwise arising out of the administration, utilization and/or ingestion of Product, sold or otherwise provided to the injured party by or under authority of Paladin (or its permitted subdistributor or contractor); or otherwise with respect to Product supplied to, or sold or distributed by, Paladin (or its permitted subdistributor or contractor), provided:
- a. Paladin shall not be obligated under this Section 18.1 if it is shown by evidence acceptable in a court of law having jurisdiction over the subject matter and meeting the appropriate degree of proof of such action, that the injury was the result of (i) gross negligence or willful misconduct of any employee or agent of VIVUS, or (ii) a breach by VIVUS of its obligations or warranties hereunder, including the supply by VIVUS of Product that fails to meet applicable Specifications;

- b. Paladin shall have no obligation under this Section 18.1 unless VIVUS (i) gives Paladin prompt written notice of any claim or lawsuit or other action for which it seeks to be indemnified by this Agreement; (ii) Paladin is granted full authority and control over the defense, including settlement, against such claim or lawsuit or other action; and (iii) VIVUS cooperates fully with Paladin and its agents in defense of the claims or lawsuit or other action; and
- c. VIVUS shall have the right to participate in the defense of any such claim, complaint, suit, proceeding or cause of action referred to in this Section 18.1 utilizing attorneys of its choice, at its own expense, provided, however, that Paladin shall have full authority and control to handle any such claim, complaint, suit, proceeding or cause of action, including any settlement or other disposition thereof, to the extent VIVUS seeks indemnification under this Section 18.1.

18.2 Indemnification by VIVUS. VIVUS shall defend, indemnify, and hold harmless Paladin, its officers, directors, shareholders, employees, successors or assigns from any loss, damage, or liability, including reasonable attorney's fees, resulting from any claim, complaint, suit, proceeding or cause of action by a Third Party against any of them alleging physical injury or death or otherwise arising out of (i) the administration, utilization and/or ingestion of Product, sold or otherwise provided to the injured party by VIVUS (or its permitted subdistributor or contractor other than by or under authority of Paladin); or (ii) the supply of VIVUS of Product that fails to meet applicable Specifications, provided:

- a. VIVUS shall not be obligated under this Section 18.2 if it is shown by evidence acceptable in a court of law having jurisdiction over the subject matter and meeting the appropriate degree of proof for such action, that the injury was the result of (i) the gross negligence or willful misconduct of any employee or agent of Paladin; or (ii) a breach by Paladin of its obligations or warranties hereunder, including the transportation, storage and distribution of Product in the Territory.
- b. VIVUS shall have no obligation under this Section 18.2 unless Paladin (i) gives VIVUS prompt written notice of any claim or lawsuit or other action for which it seeks to be indemnified under this Agreement; (ii) VIVUS is granted full authority and control over the defense, including settlement, against such claim or lawsuit or other action; and (iii) Paladin cooperates fully with VIVUS and its agents in defense of the claims or lawsuit or other action; and
- c. Paladin shall have the right to participate in the defense of any such claim, complaint, suit, proceeding or cause of action referred to in this Section 18.2 utilizing attorneys of its choice, at its own expense, provided, however, that VIVUS shall have full authority and control to handle any such claim, complaint, suit, proceeding or cause of action, including any settlement or other disposition thereof, to the extent Paladin seeks indemnification under this Section 18.2.

- d. VIVUS shall defend, indemnify, and hold harmless Paladin, its officers, directors, shareholders, employees, successors or assigns from any loss, damage, or liability, including reasonable attorney's fees, resulting from any claim, complaint, suit, proceeding or cause of action by a Third Party against any of them alleging that the price for the Product in the Territory was excessive prior to the Effective Date of this Agreement.

#### ARTICLE 19 - CONFIDENTIALITY AND DISCLOSURE

- 19.1 Confidentiality. Neither party shall use or disclose any Confidential Information received by it pursuant to this Agreement without the prior written consent of the other. This obligation shall continue for a period of seven (7) years after expiration or termination of this Agreement.
- 19.2 Disclosure. Nothing contained in this Article 19 shall be construed to restrict the parties from disclosing Confidential Information as required: (i) for regulatory, tax, securities or customs reasons, (ii) by court or other government order, (iii) for confidential audit purposes; or (iv) from using such Confidential Information as is reasonably necessary to perform acts permitted by this Agreement, including the registration, marketing, sale or use of the Product.

#### ARTICLE 20 - MISCELLANEOUS

- 20.1 Assignment. This Agreement may not be assigned or otherwise transferred, nor, except as expressly provided hereunder, may any right or obligation hereunder be assigned or transferred by either party without the prior written consent of the other party; provided, however, that either VIVUS or Paladin may, without such consent, assign this Agreement and its rights and obligations hereunder in connection with the transfer or sale of all or substantially all of its assets, its merger or consolidation or any similar transaction, and that Paladin may, without such consent, assign this Agreement and its rights and obligations hereunder to one or more of its Affiliates. Any permitted assignee shall assume all obligations of its assignor under this Agreement.
- 20.2 Sublicensees. In the event that Paladin grants sublicenses under Article 2, Paladin shall ensure that such sublicensees abide by all the obligations of Paladin contained in this Agreement to the extent that such obligations are relevant to and applicable to such sublicensees.
- 20.3 Damages. Notwithstanding any provision in this Agreement to the contrary, in no event shall a party hereto be liable to the other party for any indirect or consequential damages, including but not limited to loss of profits or business opportunity.

- 20.4 Severability. Each party intends not to violate any public policy, statutory or common law, rule, regulation, treaty or decision of any government agency or executive body thereof of any country or community or association of countries. If any term or provision of this Agreement is held to be invalid, illegal or unenforceable by a court or other governmental authority of competent jurisdiction, such invalidity, illegality or unenforceability shall not affect any other term or provision of this Agreement, which shall remain in full force and effect. The holding of a term or provision to be invalid, illegal or unenforceable in a jurisdiction shall not have any effect on the application of the term or provision in any other jurisdiction.
- 20.5 Notices. Any consent or notice required or permitted to be given or made under this Agreement by one party to the other shall be in writing, delivered personally or by facsimile (and promptly confirmed by personal delivery, first-class mail or courier), first-class mail or courier, postage prepaid (where applicable), addressed to the other party as shown below or to such other address as the addressee shall have last furnished in writing to the addresser and (except as otherwise provided in this Agreement) shall be effective upon receipt by the addressee.
- If to VIVUS: VIVUS International Limited  
c/o VIVUS, Inc.  
1172 Castro Street  
Mountain View, CA 94040  
Attention: Legal Department  
Fax: (650-934-5389)
- If to Paladin: Paladin Labs Inc.  
6111 Royalmount Avenue, Suite 102  
Montreal, Quebec, Canada H4P 2Y4  
Attention: (Jonathan Goodman)  
Fax: (514-344-4675)
- 20.6 Applicable Law. This Agreement shall be governed by and construed in accordance with the laws of the State of Delaware, excluding its conflict of laws provision. Application of the United Nations Convention On Contracts For The International Sale Of Goods is hereby excluded.
- 20.7 Entire Agreement. This Agreement contains the entire understanding of the parties with respect to the subject matter hereof. All express or implied agreements and understandings, either oral or written, heretofore made are superseded by this Agreement. Except as expressly provided elsewhere in this Agreement, this Agreement may be amended, or any term hereof modified, only by a written instrument duly executed by both parties hereto.
- 20.8 Headings. The captions to the Articles hereof are not a part of this Agreement, but are merely guides or labels to assist in locating and reading the Articles hereof.

20.9 Independent Contractors. It is expressly understood and agreed that VIVUS and Paladin are independent contractors and that the relationship between the two parties shall not constitute a partnership, joint venture or agency. Neither VIVUS nor Paladin shall have the authority to make any statement, representations or commitments of any kind, or to take any action, which shall be binding on the other, without the prior written consent of the party to do so.

20.10 Waiver. The waiver by either party of any right hereunder or of a failure to perform or breach by the other party shall not be deemed a waiver of any other right hereunder or of any other failure or breach whether of a similar nature or otherwise.

20.11 Alternative Dispute Resolution. The parties agree that any dispute that arises in connection with this Agreement that cannot be amicably resolved by the parties shall be resolved by Alternative Dispute Resolution ("ADR") pursuant to the procedure set forth in Exhibit 20.11 attached hereto.

20.12 Counterparts. This Agreement may be executed in two or more counterparts, each of which shall be deemed an original, but all of which together shall constitute one and the same instrument.

THEREFORE, the parties hereto have executed this Agreement as of the first day above written.

PALADIN LABS, INC.

VIVUS INTERNATIONAL, LTD.

By: /s/ Jonathan Goodman

By: /s/ Leland Wilson

Title: President

Title: President & CEO

Date: November 20, 2000

Date: November 20, 2000

EXHIBIT 1.5 - PATENTS

REF. NO.	TITLE/INVENTORS	COUNTRY; FILING/PUBLISHING INFO; SUMMARY	STATUS AND DEADLINES
(***)	(***)	(***)	(***)
(***)	(***)	(***)	(***)

PRICES (In United States Dollars)

	VIVUS produces up to (***) units of Product*	VIVUS produces (***) up to (***) units of Product*	VIVUS produces (***) up to (***) units of Product*	VIVUS produces (***) up to (***) units of Product*	VIVUS produces > (***) units of Product*
Sample Price per unit of Product	(***)	(***)	(***)	(***)	(***)
Minimum Supply Price per unit of Product **	(***)	(***)	(***)	(***)	(***)

\* Total VIVUS worldwide unit production of saleable finished Product in a calendar year (not only VIVUS finished Product produced for Paladin). VIVUS shall provide a certificate, signed by an officer of VIVUS, attesting to the unit production of saleable finished Product, with thirty (30) days of the end of each calendar year.

\*\* No Minimum Supply Price applies until after the first anniversary of the First Commercial Sale in the Territory.

## ALTERNATIVE DISPUTE RESOLUTION

The parties recognize that bona fide disputes as to certain matters may arise from time to time during the term of this Agreement which relate to either party's rights and/or obligations. To have such a dispute resolved by this Alternative Dispute Resolution ("ADR") provision, a party first must send written notice of the dispute to the other party for attempted resolution by good faith negotiations between their respective presidents (or their designees) of the affected subsidiaries, divisions, or business units within twenty-eight (28) days after such notice is received (all references to "days" in this ADR provision are to calendar days).

If the matter has not been resolved within twenty-eight (28) days of the notice of dispute, or if the parties fail to meet within such twenty-eight (28) days, either party may initiate an ADR proceeding as provided herein. The parties shall have the right to be represented by counsel in such a proceeding.

1. To begin an ADR proceeding, a party shall provide written notice to the other party of the issues to be resolved by ADR. Within fourteen (14) days after its receipt of such notice, the other party may, by written notice to the party initiating the ADR, add additional issues to be resolved within the same ADR.
2. Within twenty-one (21) days following receipt of the original ADR notice, the parties shall select a mutually acceptable neutral to preside in the resolution of any disputes in this ADR proceeding. If the parties are unable to agree on a mutually acceptable neutral within such period, either party may request the President of the CPR Institute for Dispute Resolution ("CPR"), 366 Madison Avenue, 14th Floor, New York, New York 10017, to select a neutral pursuant to the following procedures:
  - (a) The CPR shall submit to the parties a list of not less than five (5) candidates within fourteen (14) days after receipt of the request, along with a Curriculum Vitae for each candidate. No candidate shall be an employee, director, or shareholder of either party or any of their subsidiaries or affiliates.
  - (b) Such list shall include a statement of disclosure by each candidate of any circumstances likely to affect his or her impartiality.
  - (c) Each party shall number the candidates in order of preference (with the number one (1) signifying the greatest preference) and shall deliver the list to the CPR within seven (7) days following receipt of the list of candidates. If a party believes a conflict of interest exists regarding any of the candidates, that party shall provide a written explanation of the conflict to the CPR along with its list showing its order of preference for the candidates. Any party failing to return a list of preferences on time shall be deemed to have no order of preference.

- (d) If the parties collectively have identified fewer than three (3) candidates deemed to have conflicts, the CPR immediately shall designate as the neutral the candidate for whom the parties collectively have indicated the greatest preference. If a tie should result between two candidates, the CPR may designate either candidate. If the parties collectively have identified three (3) or more candidates deemed to have conflicts, the CPR shall review the explanations regarding conflicts and, in its sole discretion, may either (i) immediately designate as the neutral the candidate for whom the parties collectively have indicated the greatest preference, or (ii) issue a new list of not less than five (5) candidates, in which case the procedures set forth in subparagraphs 2(a) - 2(d) shall be repeated.
3. No earlier than twenty-eight (28) days or later than fifty-six (56) days after selection, the neutral shall hold a hearing to resolve each of the issues identified by the parties. The ADR proceeding shall take place at a location agreed upon by the parties. If the parties cannot agree, the neutral shall designate a location other than the principal place of business of either party or any of their subsidiaries or affiliates.
4. At least seven (7) days prior to the hearing, each party shall submit the following to the other party and the neutral:
- (a) a copy of all exhibits on which such party intends to rely in any oral or written presentation to the neutral;
  - (b) a list of any witnesses such party intends to call at the hearing, and a short summary of the anticipated testimony of each witness;
  - (c) a proposed ruling on each issue to be resolved, together with a request for a specific damage award or other remedy for each issue. The proposed rulings and remedies shall not contain any recitation of the facts or any legal arguments and shall not exceed one (1) page per issue.
  - (d) a brief in support of such party's proposed rulings and remedies, provided that the brief shall not exceed twenty (20) pages. This page limitation shall apply regardless of the number of issues raised in the ADR proceeding.

Except as expressly set forth in subparagraphs 4(a) - 4(d), no discovery shall be required or permitted by any means, including depositions, interrogatories, requests for admissions, or production of documents.

5. The hearing shall be conducted on two (2) consecutive days and shall be governed by the following rules:
- (a) Each party shall be entitled to five (5) hours of hearing time to present its case. The neutral shall determine whether each party has had the five (5) hours to which it is entitled.

- (b) Each party shall be entitled, but not required, to make an opening statement, to present regular and rebuttal testimony, documents or other evidence, to cross-examine witnesses, and to make a closing argument. Cross-examination of witnesses shall occur immediately after their direct testimony, and cross-examination time shall be charged against the party conducting the cross-examination.
  - (c) The party initiating the ADR shall begin the hearing and, if it chooses to make an opening statement, shall address not only issues it raised but also any issues raised by the responding party. The responding party, if it chooses to make an opening statement, also shall address all issues raised in the ADR. Thereafter, the presentation of regular and rebuttal testimony and documents, other evidence, and closing arguments shall proceed in the same sequence.
  - (d) Except when testifying, witnesses shall be excluded from the hearing until closing arguments.
  - (e) Settlement negotiations, including any statements made therein, shall not be admissible under any circumstances. Affidavits prepared for purposes of the ADR hearing also shall not be admissible. As to all other matters, the neutral shall have sole discretion regarding the admissibility of any evidence.
6. Within seven (7) days following completion of the hearing, each party may submit to the other party and the neutral a post-hearing brief in support of its proposed rulings and remedies, provided that such brief shall not contain or discuss any new evidence and shall not exceed ten (10) pages. This page limitation shall apply regardless of the number of issues raised in the ADR proceeding.
7. The neutral shall rule on each disputed issue within fourteen (14) days following completion of the hearing. Such ruling shall adopt in its entirety the proposed ruling and remedy of one of the parties on each disputed issue but may adopt one party's proposed rulings and remedies on some issues and the other party's proposed rulings and remedies on other issues. The neutral shall not issue any written opinion or otherwise explain the basis of the ruling.
8. The neutral shall be paid a reasonable fee plus expenses. These fees and expenses, along with the reasonable legal fees and expenses of the prevailing party (including all expert witness fees and expenses), the fees and expenses of a court reporter, and any expenses for a hearing room, shall be paid as follows:
- (a) If the neutral rules in favor of one party on all disputed issues in the ADR, the losing party shall pay 100% of such fees and expenses.

- (b) If the neutral rules in favor of one party on some issues and the other party on other issues, the neutral shall issue with the rulings a written determination as to how such fees and expenses shall be allocated between the parties. The neutral shall allocate fees and expenses in a way that bears a reasonable relationship to the outcome of the ADR, with the party prevailing on more issues, or on issues of greater value or gravity, recovering a relatively larger share of its legal fees and expenses.
9. The rulings of the neutral and the allocation of fees and expenses shall be binding, non-reviewable, and non-appealable, and may be entered as a final judgment in any court having jurisdiction.
10. Except as provided in paragraph 9 or as required by law, the existence of the dispute, any settlement negotiations, the ADR hearing, any submissions (including exhibits, testimony, proposed rulings, and briefs), and the rulings shall be deemed Confidential Information. The neutral shall have the authority to impose sanctions for unauthorized disclosure of Confidential Information.

## AGREEMENT

This Agreement made as of this 28th day of December, 2000 (hereinafter referred to as "EFFECTIVE DATE"), between TANABE SEIYAKU CO., LTD., a Japanese corporation having its principal office at 2-10 Doshomachi 3-chome, Chuo-ku, Osaka, Japan (hereinafter referred to as "TANABE") and VIVUS, INC., a corporation having its principal office at 1172 Castro Street, Mountain View, CA 94040, USA (hereinafter referred to as "VIVUS"). TANABE and VIVUS are sometimes referred to herein individually as a "Party" or collectively as "Parties".

## WITNESSETH:

WHEREAS, TANABE is the owner of all right, title and interest in certain patents and know-how relating to a selective phosphodiesterase type-5 inhibitor compound referred to by TANABE as "T-1790", and TANABE desires a collaborator to develop and market such compound;

WHEREAS, VIVUS has extensive capabilities in the development, manufacture and marketing of pharmaceutical products in the USA;

WHEREAS, TANABE and VIVUS have entered into the Secrecy Agreement effective as of the 19th day of June, 2000 (hereinafter referred to as "SECRECY Agreement"), under which TANABE has disclosed to VIVUS data and information relating to the aforesaid compound;

WHEREAS, after reviewing and taking into consideration aforesaid information, VIVUS desires to obtain the right to develop and to market the product containing the aforesaid compound; and

WHEREAS, TANABE is willing to grant the desired right to VIVUS subject to the terms and conditions hereinafter set forth.

NOW, THEREFORE, in consideration of the covenants and obligations expressed herein, and intending to be legally bound, the Parties agree as follows:

## 1. Definitions.

- 1.1 "ADVERSE DRUG REACTION" means any adverse drug reaction as defined in the then current edition of ICH Guidelines and any other relevant regulatory guidelines, whether the ADVERSE DRUG REACTION occurs in the conduct of clinical trials or is reported during post-marketing surveillance or any other means.
- 1.2 "AFFILIATE" means any corporation or other business entity which directly or

indirectly controls, or is controlled by, or under common control with a Party hereto. For the purpose of this definition, "control" means that an entity owns or controls other entity by means of fifty percent (50%) or more of the equity conferring voting rights, or otherwise has the ability to direct the business affairs of other entity.

- 1.3 "BULK DRUG TABLETS" means formulated tablets containing COMPOUND in bulk form which if appropriately packaged and labeled would constitute PRODUCT, and which shall be supplied by TANABE pursuant to Section 7.1, and which excludes RAPIDLY DISINTEGRATED TABLET unless otherwise agreed by the Parties.
- 1.4 "BULK DRUG SUBSTANCE" means COMPOUND in bulk form which, if appropriately formulated and finished, would constitute PRODUCT, and which shall be supplied by TANABE pursuant to Section 7.1.
- 1.5 "CALENDAR QUARTER" means the respective period of three (3) consecutive calendar months as used by VIVUS for financial reporting ending on or about March 31, June 30, September 30 and December 31.
- 1.6 "CALENDAR YEAR" means the respective period of about a year as used by VIVUS for financial reporting commencing on January 1 and ending on December 31.
- 1.7 "CLINICAL STUDIES" means PHASE I CLINICAL STUDIES, PHASE II CLINICAL STUDIES and PHASE III CLINICAL STUDIES.
- 1.8 "COMPOUND" means all the compounds which are selective phosphodiesterase type-5 inhibitor, which compounds are contained within a claim of any unexpired TANABE PATENT no matter when filed or in a claim of a pending application for a TANABE PATENT no matter when filed which is being prosecuted in good faith by or on behalf of TANABE or its AFFILIATE, including without limitation the compound coded as T-1790 by TANABE, chemically known as (\*\*\*) .
- 1.9 "CONTROL" or "CONTROLLED" means the right to grant a license or sublicense to intangible property rights (including patent rights, know-how and trade secret INFORMATION), and the right to provide access to or cross-reference to regulatory filings, in each case to the extent not in violation of the terms of any pre-existing agreement or other arrangement with any THIRD PARTY. "CONTROL" expressly includes the right of ownership, in whole or in part.
- 1.10 "DATE OF FIRST SALE" means the date on which the PRODUCT is first sold in a country in the TERRITORY by VIVUS to a THIRD PARTY (other than

VIVUS' SUBLICENSEES) in a commercial arms length transaction.

- 1.11 "DEVELOPMENT PLAN" means the plan for development of the COMPOUND into a PRODUCT in the TERRITORY which is established pursuant to Section 5.6.
- 1.12 "DEVELOPMENT WORK" means all activities relating to obtaining REGULATORY APPROVAL, and activities relating to manufacture of the BULK DRUG SUBSTANCE and PRODUCTS, including but not limited to activities relating to preclinical test, toxicology, pharmacokinetics, CLINICAL STUDIES, manufacturing process, formulation, quality assurance, quality control and regulatory affairs.
- 1.13 "DRUG APPROVAL APPLICATION" means an application for product license approvals, health registrations, marketing authorizations, regulatory submissions, notices of compliance and other licenses and permits (NDA and the like) required to be approved before commercial sale or use of a PRODUCT as a drug in a regulatory jurisdiction.
- 1.14 "EFFECTIVE DATE" means the date first written above.
- 1.15 "EMEA" means The European Agency for the Evaluation of Medicinal Products or any successor entity.
- 1.16 "EUROPEAN UNION" means a part of or all of the countries which are then current members of the European Union.
- 1.17 "FIELD" means treatment of male erectile dysfunction or female sexual dysfunction in humans.
- 1.18 "FDA" means the United States Food and Drug Administration or any successor entity.
- 1.19 "IND" means an Investigational New Drug Application filed with the FDA or a corresponding application filed with a regulatory agency with respect to development of a COMPOUND into a PRODUCT in the FIELD applicable in any country in the TERRITORY.
- 1.20 "INFORMATION" means all information, techniques, data, inventions, practices, methods, knowledge, know-how, skill, experience, patent applications or test data, generally not known to the public, relating to the FIELD, which is owned or CONTROLLED by a Party relating to the COMPOUND or a PRODUCT which includes (but not limited to), pharmacological, toxicological, preclinical and clinical test data, analytical and quality control data, packaging, marketing, pricing, distribution, sales and manufacturing data or descriptions,

compositions-of-matter of the COMPOUND, assays and biological materials related thereto.

- 1.21 "MAJOR EUROPEAN COUNTRY" means the United Kingdom, Germany, France, Italy and Spain.
- 1.22 "MANUFACTURING COST" shall mean the manufacturing cost of the BULK DRUG SUBSTANCE, which is manufactured by or on behalf of TANABE (or the PRODUCT manufactured and supplied by or on behalf of VIVUS under Section 8.5), and which includes the following:
- (a) Materials Cost, which means the price paid for raw material components and finished goods which are purchased from outside vendors as well as any freight and duty where applicable.
  - (b) Direct Labor Costs, which means the employment costs attributable to manufacturing the BULK DRUG SUBSTANCE including, without limitation, salary and employee benefits within the relevant manufacturing operating unit.
  - (c) Overhead Costs, which means the cost of specific activities attributable to manufacturing the BULK DRUG SUBSTANCE that are provided by support functions and are performed at a frequency which is in correlation with the production. Overhead Costs includes, expenses associated with quality assurance testing, batch review, equipment maintenance costs, manufacturing utilities, waste removal, management and administrative expenses, general facilities costs, environmental engineering, property taxes and insurance.
  - (d) Equipment Depreciation, which means the amortization of the costs of specific manufacturing facility, machinery or equipment dedicated either solely or partly (on a pro rata basis) to the production, calculated in accordance with the applicable generally accepted accounting practices.

It is understood and agreed that the definition of MANUFACTURING COST shall be consistently applied during the term of the Agreement.

- 1.23 "NDA" means a New Drug Application submitted to the FDA in the United States for the PRODUCT.
- 1.24 "NET SALES" means:
- (a) with respect to a PRODUCT, the amount invoiced by VIVUS, its AFFILIATES and their SUBLICENSEES for sales of a PRODUCT to a THIRD PARTY in the TERRITORY in a commercial arms length

transaction, less estimates which will be adjusted to actual on a periodic basis of: (i) discounts, including cash discounts, rebates paid, credit accrued or actually taken, and retroactive price reductions or allowances actually allowed or granted from the billed amount, and commercially reasonable and customary fees paid to distributors (other than to a distributor that is an AFFILIATE of VIVUS), (ii) credits or allowances actually granted upon claims, rejections or returns of such sales of PRODUCT, including recalls, regardless of VIVUS requesting such recalls, and (iii) taxes, duties or other governmental charges levied on or measured by the billing amount when included in billing, as adjusted for the items of (i) and (ii) above.

- (b) It is understood and agreed that sales or transfers of PRODUCTS between VIVUS, its AFFILIATES and their SUBLICENSEES shall not constitute a "NET SALES" unless such party is an end-user of such product.
- (c) For the avoidance of doubt, even if the NON-ORAL PRODUCT is sold in combination with any other active ingredient than the COMPOUND, full NET SALES for such combination NON-ORAL PRODUCT shall be applicable for the calculation of supply price under Section 11.

- 1.25 "NON-ORAL PRODUCT" means the PRODUCT other than the ORAL PRODUCT, which NON-ORAL PRODUCT includes, without limitation, the transurethral product and the topical product.
- 1.26 "ORAL PRODUCT" means the PRODUCT in oral formulation.
- 1.27 "PDE5 INHIBITOR" means a phosphodiesterase type-5 inhibitor.
- 1.28 "PHASE I CLINICAL STUDIES" means that portion of the clinical DEVELOPMENT PLAN or DEVELOPMENT WORK which provides for the first introduction into humans of a COMPOUND or PRODUCT including one or more small scale clinical studies conducted in normal volunteers or patients to get INFORMATION on PRODUCT safety, tolerability, pharmacological activity or pharmacokinetics as more fully defined in 21 C.F.R. 312.21(a).
- 1.29 "PHASE II CLINICAL STUDIES" means that portion of the clinical DEVELOPMENT PLAN or DEVELOPMENT WORK, which provides for the definitive, well controlled clinical trials of a COMPOUND or PRODUCT in patients, including one or more clinical studies conducted in patients and designed to indicate clinical efficacy and safety for a PRODUCT for one or more indications, as well as to obtain an indication of the dosage regimen required, as more fully defined in 21 C.F.R. 312.21(b).
- 1.30 "PHASE III CLINICAL STUDIES" means that portion of the clinical

DEVELOPMENT PLAN or DEVELOPMENT WORK which provides for one or more large scale clinical studies conducted in a sufficient number of patients to establish a PRODUCT's clinical efficacy and safety for one or more indications, as more fully defined in 21 C.F.R. 312.21(c).

- 1.31 "POST REGISTRATION STUDIES" means clinical studies which are conducted in a particular country after the obtainment of REGULATORY APPROVAL from the appropriate regulatory agency in that country, which studies are conducted for the purpose of enhancing commercial acceptability of a PRODUCT.
- 1.32 "PRODUCT" means any product which has been manufactured into a final dosage form, packaged and labeled for use in the FIELD, and which contains the COMPOUND as an active ingredient.
- 1.33 "RAPIDLY DISINTEGRATED TABLET" means the COMPOUND in bulk tablet formulation which, if appropriately packaged and finished, would constitute the PRODUCT, which has the feature of disintegrating in the mouth and can be administered without the use of water.
- 1.34 "REGULATORY APPROVAL" means all official approvals by government, pricing or health authorities in a country (or supra-national organizations, such as the EMEA) which are required for first sale, including, importation or manufacture of a PRODUCT in such country where required.
- 1.35 "SPECIFICATIONS" means the specifications for the supply of the BULK DRUG SUBSTANCE and BULK DRUG TABLETS to VIVUS, a draft of which is attached hereto as Appendix-E, and which shall be amended from time to time as agreed by the Parties and in accordance with the terms of this Agreement.
- 1.36 "STEERING COMMITTEE" means representatives from TANABE and VIVUS who are designated respectively by each Party to review the development and marketing of the PRODUCT in the TERRITORY pursuant to Article 4.
- 1.37 "SUBLICENSEE" means, with respect to a particular PRODUCT, a THIRD PARTY to whom VIVUS or TANABE has granted a license or sublicense under any TANABE PATENTS, VIVUS PATENTS or INFORMATION to make and sell such PRODUCT.
- 1.38 "TANABE KNOW-HOW" means all INFORMATION that TANABE discloses to VIVUS under this Agreement and is within the CONTROL of TANABE. It is understood and agreed that TANABE KNOW-HOW does not include TANABE PATENTS.
- 1.39 "TANABE PATENT" means the patent which is attached hereto as Appendix A,

and any other valid U.S. and foreign patents relating thereto, including without limitation, all substitutions, reissues, renewals, reexaminations, patents of addition, extensions, registrations, confirmations, and all pending patent applications, (including provisional applications, continuations, divisionals and continuation-in-part), which is owned or CONTROLLED by TANABE or its AFFILIATES as of the EFFECTIVE DATE or during the term of this Agreement. The "TANABE PATENT" shall include but not be limited to patents directed to new uses of the compounds claimed within the TANABE PATENT in the FIELD, and patents directed to manufacturing and formulation of the compounds claimed within the TANABE PATENT in the FIELD unless otherwise set forth herein. Notwithstanding anything herein to the contrary, the "TANABE PATENT" shall expressly exclude any claims within patents directed to formulations of the RAPIDLY DISINTEGRATED TABLET whether made by or on behalf of TANABE or its AFFILIATES before or after the EFFECTIVE DATE.

- 1.40 "TERRITORY" means all the countries in the world excluding Japan, Democratic People's Republic of Korea (North Korea), Republic of Korea (South Korea), People's Republic of China (PRC including Hong Kong and Macao), Republic of China (Taiwan), Singapore, Indonesia, Malaysia, Thailand, Vietnam and the Philippines.
- 1.41 "THIRD PARTY" means any entity other than TANABE or VIVUS or their respective AFFILIATES.
- 1.42 "TRADEMARK" means the trademark which shall be used for the marketing of the PRODUCT in the TERRITORY, which trademark may be the same or different from the trademark used for the marketing of the PRODUCT outside the TERRITORY.
- 1.43 "VIVUS KNOW-HOW" means all INFORMATION which VIVUS discloses to TANABE under this Agreement and is within the CONTROL of VIVUS. It is understood and agreed that VIVUS KNOW-HOW does not include VIVUS PATENTS.
- 1.44 "VIVUS PATENT" means valid U.S. and foreign patents, including without limitation, all substitutions, reissues, renewals, reexaminations, patents of addition, extensions, registrations, confirmations, and all pending patent applications, (including provisional applications, continuations, divisionals and continuation-in-part), which, absent rights thereunder, would be infringed by the research, development, manufacture, use, importation, sale or offer for sale of a COMPOUND or a PRODUCT in the FIELD, and is owned or CONTROLLED by VIVUS or its AFFILIATE as of the EFFECTIVE DATE or during the term of this Agreement. The "VIVUS PATENT" shall include but not limited to patents directed to new uses of the COMPOUND or PRODUCT in the FIELD, and

patents directed to formulating the PRODUCT in the FIELD.

2. Grant of Right.

- 2.1 Grant of License under TANABE PATENT and TANABE KNOW-HOW. TANABE hereby grants to VIVUS, and VIVUS hereby accepts, an exclusive license, with the right to grant and authorize sublicenses pursuant to Section 2.3, to develop, manufacture, have manufactured, use, import, sell, offer to sell, register and market the PRODUCT (or the COMPOUND where applicable) in the FIELD in the TERRITORY under the TANABE PATENT and the TANABE KNOW-HOW. However, it is expressly understood between the Parties that VIVUS shall not have the right to manufacture the BULK DRUG SUBSTANCE or BULK DRUG TABLETS unless otherwise agreed.
- 2.2 Extension of the License to AFFILIATE. VIVUS shall have the right to extend its rights under the license granted hereunder to one or more of its AFFILIATES, provided, that VIVUS shall (i) notify TANABE the names of such AFFILIATE reasonably prior to such extension, (ii) retain control over that portion of DEVELOPMENT WORK which such AFFILIATE is performing and (iii) remain responsible to TANABE for such AFFILIATE's compliance with all obligations under this Agreement which apply to such AFFILIATE.
- 2.3 Sublicense. VIVUS may grant sublicenses under the license granted under Section 2.1 to one or more THIRD PARTIES; provided, VIVUS: (i) notifies and consults with TANABE with respect to the selection of SUBLICENSEES, (ii) uses its reasonable efforts to sublicense to a THIRD PARTY that will maximize the sale of PRODUCTS, and (iii) uses its best efforts to include in any such sublicense the obligation that such SUBLICENSEE not develop or commercialize or in-license another PDE5 INHIBITOR compound for a period of five (5) years following the effective date of such sublicense agreement. VIVUS shall (i) retain control over that portion of DEVELOPMENT WORK which such SUBLICENSEE is performing, if any, and (ii) remain responsible to TANABE for such SUBLICENSEE's compliance with all obligations under this Agreement which apply to such SUBLICENSEE. In case of sublicense to a THIRD PARTY, the performance of the obligations of any such SUBLICENSEE shall be deemed guaranteed by VIVUS.
- 2.4 Tanabe's Co-Promotion Right. Notwithstanding the foregoing Section 2.1, TANABE shall have the option to obtain the right to co-promote with VIVUS or its SUBLICENSEE up to (\*\*\*) of the promotional efforts in the TERRITORY for the ORAL PRODUCT, such option to be exercised and negotiated within five (5) months following VIVUS' disclosure to TANABE of the data and report for such ORAL PRODUCT following completion of the first successful PHASE II CLINICAL STUDY for such ORAL PRODUCT. The terms of such agreement shall be negotiated in good faith and reasonably agreed by both parties. The promotional efforts of each Party shall be determined by

market potential as well as the marketing strength of each Party and its AFFILIATES (or SUBLICENSEE in case of VIVUS) in that country or region.

2.5 License under VIVUS PATENT and VIVUS KNOW-HOW to TANABE for PRODUCT. VIVUS hereby grants to TANABE the following right under VIVUS PATENT and VIVUS KNOW-HOW:

- (a) for the term of this Agreement and thereafter, an exclusive and royalty-free license to develop, make, have made, use, import, sell, offer to sell, register and market any ORAL PRODUCT being developed or sold hereunder by VIVUS, with a right to sublicense, solely outside the TERRITORY in the FIELD.
- (b) during the term of this Agreement, an exclusive option to obtain an exclusive license to develop, use, import, sell, offer to sell, register and market any NON-ORAL PRODUCT being developed or sold hereunder by VIVUS, with a right to sublicense, outside the TERRITORY in the FIELD for the term of this Agreement and thereafter. The terms and conditions of such license shall be negotiated in good faith and shall be based on reasonable terms common in the pharmaceutical industry, including a reasonable royalty payable to VIVUS for using the VIVUS PATENT and VIVUS KNOW-HOW relating to such NON-ORAL PRODUCT.
- (c) during the term of this Agreement and thereafter, a semi-exclusive and royalty-free license to use, import, sell, offer to sell, register and co-promote any COMPOUND or PRODUCT being developed or sold hereunder by VIVUS in the TERRITORY, solely to the extent that TANABE elects and is granted the right to perform co-promotion of such PRODUCT pursuant to Section 2.4.

Should royalties be due to a THIRD PARTY under any sublicense granted to TANABE hereunder, TANABE shall be obligated to pay such royalties and comply with all terms and conditions of such THIRD PARTY license.

2.6 Non-compete. VIVUS agrees not to develop, market, in-license or out-license any PDE5 INHIBITOR compounds other than the COMPOUNDS, for use in the FIELD during the term of this Agreement. TANABE shall have the right to in-license and/or conduct pre-clinical work on any PDE5 INHIBITOR compounds, other than the COMPOUNDS, for use in the FIELD (each a "Next Generation Compound"); provided, TANABE shall grant to VIVUS an exclusive right of first refusal to conduct clinical studies in order to develop and commercialize within the TERRITORY such Next Generation Compounds owned or CONTROLLED by TANABE. Such right may be exercised by VIVUS within four (4) years after first commercial sale of a PRODUCT by VIVUS. The terms of such agreement shall be negotiated in good faith and mutually agreeable to both Parties; provided, in no event shall VIVUS be required to pay any upfront licensing fee and any milestone fees for the rights to such Next Generation

Compound, which fees it has already paid under the terms of this Agreement for the COMPOUND (e.g. if VIVUS elects to license in a Next Generation Compound after it has already paid the PHASE II CLINICAL STUDY milestone for a COMPOUND, then it shall have no obligation to pay a milestone payment upon commencement of PHASE II CLINICAL STUDIES for such Next Generation Compound). It is understood and agreed that during such period (i.e. four (4) years after first commercial sale of a PRODUCT by VIVUS), TANABE and its AFFILIATES may not grant a THIRD PARTY the right to conduct clinical studies on Next Generation Compounds in any country in the world; provided, if VIVUS exercises its right of first refusal to a particular Next Generation Compound pursuant to this Section, TANABE shall have the right to grant a THIRD PARTY the right to conduct clinical studies on such Next Generation Compound solely outside TERRITORY.

### 3. Disclosure and Exchange of INFORMATION.

3.1 Disclosure of INFORMATION. Within forty five (45) days following the EFFECTIVE DATE, TANABE shall disclose and make available to VIVUS without charge, all preclinical, clinical or regulatory INFORMATION, including copies of all preclinical and clinical reports, (i) which is known by TANABE, (ii) which directly concerns the COMPOUND or the PRODUCT and (iii) which TANABE in its commercially reasonable sole discretion considers to be useful or necessary for VIVUS to exercise the license granted under Article 2. Thereafter, during the term of the Agreement, each Party shall disclose and make available to the other Party without charge, all relevant INFORMATION, including copies of all preclinical and clinical reports, known by such Party which in its commercially reasonable sole discretion it considers to be useful or necessary for the other Party to exercise the rights and licenses expressly granted herein. The exchanges of INFORMATION hereunder shall be undertaken in written or oral form as soon as reasonably possible after the obtainment thereof, as necessary, and through regular meetings. The initial disclosure and the exchanges of INFORMATION hereunder shall be (i) made in English, (ii) undertaken in written form as soon as reasonably possible after the obtainment thereof, (iii) treated as confidential information of the Party disclosing such INFORMATION subject to Article 18 and (iv) made in the following manner:

- (a) the Party disclosing the INFORMATION (hereinafter referred to as the "Disclosing Party") shall provide to the other Party (hereinafter referred to as the "Receiving Party") the list of the INFORMATION in English.
- (b) promptly upon the receipt of such list, the Receiving Party shall indicate to the Disclosing Party, in writing, the items in the list, of which it desires to receive the content from the Disclosing Party, and
- (c) promptly after the receipt of the notice indicating the items from the Receiving Party, the Disclosing Party shall provide to the Receiving Party

the content of the items which were indicated pursuant to foregoing Section 3.1(b).

Each Party agrees not to use INFORMATION disclosed by the other Party, other than for the rights and licenses expressly granted herein. Notwithstanding the foregoing, INFORMATION relating to the manufacture of the BULK DRUG SUBSTANCE or BULK DRUG TABLETS need not be disclosed by TANABE, except as required for regulatory filings, submissions, approvals and/or audits.

- 3.2 TANABE INFORMATION Disclosure Prior to the EFFECTIVE DATE. TANABE represents and warrants that it has produced or provided access to VIVUS prior to the EFFECTIVE DATE all material INFORMATION relating to the safety of the COMPOUND or the PRODUCT, including, but not limited to, material INFORMATION concerning ADVERSE DRUG REACTION, toxicity or sensitivity reactions and incidents and the severity thereof with respect to any tests or studies conducted by TANABE or its contractors relating to the COMPOUND or the PRODUCT. In addition, TANABE represents and warrants that it has provided access to VIVUS prior to the EFFECTIVE DATE, all material INFORMATION, relating to the efficacy of the COMPOUND and the PRODUCT and preclinical and clinical work and studies relating to the COMPOUND and the PRODUCT.
- 3.3 Disclosure of INFORMATION from THIRD PARTY. In case either Party hereto intends to have the research, development, manufacture, use or marketing of the COMPOUND or the PRODUCT conducted by any THIRD PARTY or otherwise license such right to any THIRD PARTY (to the extent permitted under this Agreement), such Party shall include in the agreement to be concluded with such THIRD PARTY a provision allowing such Party to disclose to and have used by the other Party any and all information, techniques, data, inventions, practices, methods, knowledge, know-how, skill, experience or test data relating to COMPOUND or PRODUCT for use in the FIELD which is disclosed to such Party by such THIRD PARTY.

4. STEERING COMMITTEE.

The STEERING COMMITTEE shall have the primary role in ensuring the success of the PRODUCT, during the development and marketing in the TERRITORY. The STEERING COMMITTEE will operate in accordance with the STEERING COMMITTEE Guidelines attached hereto as Appendix-C.

5. Development.

- 5.1 DEVELOPMENT WORK. VIVUS shall, at its own cost and expense, conduct the DEVELOPMENT WORK to seek REGULATORY APPROVAL of the PRODUCTS in the TERRITORY. VIVUS shall not, however, be responsible for DEVELOPMENT WORK as it relates to seeking REGULATORY APPROVAL of the PRODUCTS outside the TERRITORY or the manufacturing scale-up and

production of validation batches of the BULK DRUG TABLETS (or the BULK DRUG SUBSTANCE where applicable). Rather, such shall be TANABE's responsibility at its own costs and expense. Such work as the manufacturing scale-up, production of validation batches and the manufacture of the BULK DRUG TABLETS and BULK DRUG SUBSTANCE shall be carried out by TANABE using reasonable commercial efforts and in a timely manner in accordance with the DEVELOPMENT PLAN so as not to delay VIVUS' initiation of CLINICAL STUDIES, filing of DRUG APPROVAL APPLICATIONS or launch of the PRODUCTS. It is understood and agreed by the Parties that VIVUS may conduct its activities under this Article 5 by itself or through its designees, subject to TANABE's prior approval, such approval not to be unreasonably withheld. TANABE agrees to act promptly in evaluating potential designees and in no case shall take more than ten (10) business days to render its decision.

- 5.2 CLINICAL STUDIES Protocols. VIVUS shall inform TANABE, in writing, of the draft protocol for such CLINICAL STUDIES for TANABE's review and consideration, before commencement of any CLINICAL STUDIES for the COMPOUND or the PRODUCTS conducted by it in the TERRITORY. Once so informed, TANABE will have ten (10) business days to review and provide comments on the draft protocol. In addition, should TANABE request any change or addition to such draft protocol for the purpose of using the data generated under the DEVELOPMENT WORK in the TERRITORY for TANABE's development outside the TERRITORY, then TANABE shall promptly notify VIVUS to such effect, and VIVUS shall accommodate such request to the extent such request is reasonably acceptable by VIVUS. If such request causes additional costs to VIVUS, TANABE shall reimburse such additional costs to VIVUS in full.
- 5.3 DRUG APPROVAL APPLICATION and REGULATORY APPROVAL. VIVUS shall use commercially reasonable efforts to undertake the compilation, submission and prosecution, in timely manner, of all necessary data, documents and DRUG APPROVAL APPLICATION in a format acceptable to the applicable regulatory authorities in the TERRITORY, including but not limited to the FDA and the EMEA, required to obtain REGULATORY APPROVAL for the PRODUCTS for use in the FIELD. This shall include obtaining all necessary labeling for the PRODUCTS. In addition, VIVUS shall use commercially reasonable efforts to maintain the REGULATORY APPROVAL obtained under this Section 5.3. VIVUS shall solely own all such DRUG APPROVAL APPLICATION and REGULATORY APPROVAL in the TERRITORY. VIVUS shall collaborate with TANABE to the extent legally permitted, in order to enable TANABE to prepare, if necessary, DRUG APPROVAL APPLICATION in the FIELD, and obtain, if necessary, REGULATORY APPROVALS for the PRODUCTS outside the TERRITORY.

- 5.4 Costs and Expense. VIVUS shall be fully responsible for bearing all costs and expense associated with undertaking and completing said registration activities in the TERRITORY, including but not limited to the costs of preparing and prosecuting DRUG APPROVAL APPLICATION and fees payable to regulatory agencies in obtaining and maintaining REGULATORY APPROVAL. TANABE shall be fully responsible for bearing all costs and expense associated with undertaking and completing said registration activities outside of the TERRITORY, including but not limited to the costs of preparing and prosecuting DRUG APPROVAL APPLICATION and fees payable to regulatory agencies in obtaining and maintaining REGULATORY APPROVAL.
- 5.5 Diligence. VIVUS shall use such diligence as giving the first or top priority to the development of the COMPOUND into the PRODUCT and the obtainment of its REGULATORY APPROVAL, among those products which are then developed by its clinical development team for urinary diseases. If TANABE in its reasonable judgment concludes that VIVUS has failed with respect to such diligence, it shall notify VIVUS in writing and VIVUS shall have ninety (90) days to cure such failure. If VIVUS has not cured such failure within such time, and if such failure cannot be justified in a commercially reasonable manner consistent with the pharmaceutical business and scientific judgment (which cause includes but not limited to such case where the result of the CLINICAL STUDIES negatively and drastically affects the commercial potential of the PRODUCT), such failure may constitute a breach of this Agreement and TANABE may terminate this Agreement pursuant to the terms of Section 20.2. It is understood and agreed that any dispute arising out of the interpretation or enforcement of this Section shall be settled by arbitration pursuant to the provisions of Article 28.
- 5.6 DEVELOPMENT PLAN. VIVUS shall prepare, in consultation with TANABE, and provide to the STEERING COMMITTEE, within sixty (60) days after the EFFECTIVE DATE, a reasonably detailed DEVELOPMENT PLAN proposal pursuant to which the DEVELOPMENT WORK will be performed. The STEERING COMMITTEE shall review such proposal and approve an initial DEVELOPMENT PLAN, with such changes as the STEERING COMMITTEE agree to the plan proposed by VIVUS, no later than thirty (30) days after its submission by VIVUS, such initial DEVELOPMENT PLAN to be attached hereto as Exhibit B. The STEERING COMMITTEE shall review and update the DEVELOPMENT PLAN from time to time as necessary.
- 5.7 Development Milestone. If any of the following milestones is in jeopardy of not being met in the United States or in any of the MAJOR EUROPEAN COUNTRY, the STEERING COMMITTEE shall discuss and determine the action plan to catch up with such milestone in jeopardy.

Milestone  
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Timing  
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- |   |  |
|---|--|
| (a) Commencement of the first PHASE II CLINICAL STUDIES for any PRODUCT.  | Date, which represents six (6) months after the commencement of PHASE II CLINICAL STUDIES set forth in the initial DEVELOPMENT PLAN, to be provided once the DEVELOPMENT PLAN is agreed upon pursuant to Section 5.6.  |
| (b) Commencement of the first PHASE III CLINICAL STUDIES for any PRODUCT. | Date, which represents six (6) months after the commencement of PHASE III CLINICAL STUDIES set forth in the initial DEVELOPMENT PLAN, to be provided once the DEVELOPMENT PLAN is agreed upon pursuant to Section 5.6. |

5.8 Submission of the Files relating to the REGULATORY APPROVAL. VIVUS shall promptly furnish TANABE with copies of all the files submitted to the competent authorities to apply for the REGULATORY APPROVAL, copies of the certificates of the REGULATORY APPROVAL obtained, and any communications received from or decisions made by the competent authorities.

## 6. Marketing.

6.1 Marketing Efforts. VIVUS agrees to use (i) commercially reasonable efforts consistent with its normal business practices to maximize the market potential of the PRODUCT and (ii) at least the same efforts in any and all aspects including without limitation, call number, budget and promotional cost, as it uses to market its own products. VIVUS agrees to use its best commercial efforts to market the PRODUCT within six (6) months of REGULATORY APPROVAL for such PRODUCT in each country in the TERRITORY.

With respect to any country in the TERRITORY, if VIVUS does not launch a PRODUCT within three (3) years after the earliest DATE OF FIRST SALE of such PRODUCT in the United States or any MAJOR EUROPEAN COUNTRY, VIVUS agrees that the license granted hereunder in such country for such PRODUCT shall revert to TANABE upon request by TANABE, unless VIVUS can reasonably justify that, with respect to such country in the TERRITORY, (i) the launch of such PRODUCT within three (3) years would be detrimental to the global development and commercial viability of such PRODUCT or (ii) the launch of the PRODUCT within three (3) years has not been achieved due to the REGULATORY APPROVAL not being obtained in spite of VIVUS' continuous efforts pursuant to Section 5.5 and the foregoing provisions of the first paragraph of this Section 6.1, or (iii) the launch of the PRODUCT within three (3) years has not been achieved due to other governmental constraints and/or controls.

- 6.2 POST-REGISTRATION STUDIES. VIVUS shall have the right to conduct by itself or through its designee POST-REGISTRATION STUDIES in the TERRITORY for PRODUCTS sold by VIVUS, its AFFILIATES or its SUBLICENSEES. If VIVUS decides to conduct POST-REGISTRATION STUDIES, VIVUS shall inform TANABE and shall take TANABE's opinion into due consideration in conducting such studies. The results of such POST-REGISTRATION STUDIES will be fully shared with TANABE. ADVERSE DRUG REACTIONS and all other safety INFORMATION occurring in POST-REGISTRATION STUDIES will be reported as described in Article 19.
- 6.3 Pricing, Pricing Approvals and PRODUCT Distribution. To the extent reasonably possible and beneficial for the marketability of the PRODUCT, VIVUS shall use its reasonable efforts to obtain the optimum pricing or reimbursement price for PRODUCTS. VIVUS shall set all optimum prices for all PRODUCTS in the TERRITORY and shall be responsible for distribution of each PRODUCT in the TERRITORY and shall record all sales for PRODUCTS in the TERRITORY.
- 6.4 Product Recalls. If VIVUS believes that a recall of a PRODUCT sold by it is necessary, VIVUS shall promptly undertake such recall following notification to TANABE. The decision of VIVUS concerning such recall shall be final. Likewise, if TANABE believes that a recall of a PRODUCT sold by it outside of the TERRITORY is necessary, TANABE may promptly undertake such recall following notification to VIVUS. The decision of TANABE concerning such recall shall be final.
- 6.5 Advertising and Promotion. With respect to printed promotional materials (including advertisements appearing in journals or internets), printed educational materials, PRODUCT labeling, and documentary INFORMATION, TANABE's name shall appear on such materials and reference to TANABE shall be in the form that references TANABE as the licensor, provided such is permitted by the applicable laws and regulations. All promotional and advertising materials to be used by VIVUS for the PRODUCT to be sold by it which includes but not limited to the materials mentioned above, shall be prepared by VIVUS or its designee at their own costs and expense. VIVUS shall send to TANABE copies of such materials for the PRODUCT to be sold by it prior to its use.
- 6.6 Sales Forecast and Marketing Strategies. VIVUS shall inform TANABE, six (6) months in advance, of a sales forecast as well as marketing strategies for the PRODUCT for each CALENDAR YEAR. TANABE may give VIVUS opinions and suggestions to assist VIVUS' activities for marketing of the PRODUCT. Such forecasts may be adjusted quarterly by VIVUS.
- 6.7 Reports on Marketing. VIVUS shall promptly render to TANABE the following

reports:

- (a) Semi-annual reports on the sales of the PRODUCT sold by VIVUS in terms of units and value,
- (b) Semi-annual reports on the quantities of the BULK DRUG SUBSTANCE and the PRODUCT held by VIVUS in their inventories, and
- (c) Reports, when requested by TANABE, outlining the situation of competitors' products and other market information relating to the PRODUCT in the TERRITORY.

7. Manufacture and Supply of the BULK DRUG TABLETS and BULK DRUG SUBSTANCE.

- 7.1 Manufacture and Supply of the BULK DRUG TABLETS and BULK DRUG SUBSTANCE. TANABE shall use its commercially reasonable efforts to manufacture and supply to VIVUS, either by itself or by a THIRD PARTY manufacturer, BULK DRUG TABLETS for the ORAL PRODUCT and BULK DRUG SUBSTANCE for the formulation and manufacturing of NON-ORAL PRODUCTS. Detailed conditions for manufacture and supply of the BULK DRUG TABLETS and BULK DRUG SUBSTANCE shall be set forth in Appendix-D.
- 7.2 Supply during CLINICAL STUDIES. TANABE shall supply the BULK DRUG SUBSTANCE reasonably needed by VIVUS for pre-clinical studies and CLINICAL STUDIES. The BULK DRUG SUBSTANCE shall be supplied, (i) free of charge, for all pre-clinical studies, PHASE I CLINICAL STUDIES and PHASE II CLINICAL STUDIES, and (ii) at the price of (\*\*\*) per kilogram (\*\*\*) (FCA place of manufacture, Incoterms 2000) for all PHASE III CLINICAL STUDIES, or to the extent necessary, validation for manufacture of the PRODUCTS.
- 7.3 Manufacture of the BULK DRUG SUBSTANCE and BULK DRUG TABLETS by a THIRD PARTY. In the event TANABE fails to supply BULK DRUG SUBSTANCE and/or BULK DRUG TABLETS to VIVUS (i) for conducting CLINICAL STUDIES, or (ii) that meet the SPECIFICATIONS, or (iii) for fulfilling market demand for the PRODUCTS, the Parties shall meet and discuss in good faith a remedy for such failure. In the event that TANABE is unable to cure such failure within a reasonable period of time, VIVUS shall have the right to designate a THIRD PARTY manufacturer, reasonably acceptable to TANABE, to manufacture and supply the BULK DRUG SUBSTANCE and/or BULK DRUG TABLETS, as applicable, to VIVUS. In such event, TANABE shall provide reasonable assistance to VIVUS and such THIRD PARTY manufacturer to ensure that supply of the BULK DRUG SUBSTANCE and/or BULK DRUG

TABLETS to VIVUS is not unreasonably disrupted. TANABE shall maintain a commercially reasonable quantity of BULK DRUG SUBSTANCE and BULK DRUG TABLETS at two remote locations in order to ensure a continuous adequate supply of each to VIVUS.

8. Manufacture of the PRODUCT.

- 8.1 Manufacture of the PRODUCT. VIVUS shall be responsible for manufacturing the PRODUCT using the BULK DRUG SUBSTANCE and BULK DRUG TABLETS supplied by TANABE pursuant to Article 7. It is understood and agreed that VIVUS' manufacture of the PRODUCT using BULK DRUG TABLETS shall be limited to packaging and labeling of such PRODUCTS.
- 8.2 Inspection of Samples by TANABE. TANABE shall have the right to be provided with reasonable quantities of free of charge samples of the PRODUCT in order to inspect the packaging of the PRODUCT, such quantities to be mutually agreed by the Parties.
- 8.3 Manufacture of the PRODUCT by a THIRD PARTY. In case VIVUS wishes to have manufactured the PRODUCT hereunder from the BULK DRUG SUBSTANCE or BULK DRUG TABLETS by a THIRD PARTY manufacturer, VIVUS shall inform TANABE of the name of such THIRD PARTY. TANABE shall have the right to approve or reject within sixty (60) days after receipt of such written notification indicating the name of such THIRD PARTY, such approval not to be unreasonably withheld, provided that in the event VIVUS does not receive a written answer from TANABE indicating its approval or rejection of such THIRD PARTY within such sixty (60) days period, TANABE shall be deemed to have approved the appointment of such THIRD PARTY.
- 8.4 Inspection of the Plants. Each Party may upon reasonable notice to the other Party inspect the plant and premises used by, and processes and records of the packaging or storage employed by a Party (or THIRD PARTY manufacturer where applicable) in connection with the BULK DRUG SUBSTANCE, BULK DRUG TABLETS, or the PRODUCT, as applicable.
- 8.5 Supply of the NON-ORAL PRODUCT to TANABE. If TANABE wishes to purchase the NON-ORAL PRODUCT manufactured by or on behalf of VIVUS pursuant to Section 8.1 for use in its development, registration, use, sale or marketing outside the TERRITORY and in the FIELD, VIVUS shall supply TANABE, to the extent possible, with the NON-ORAL PRODUCT on terms to be negotiated pursuant to Section 2.5(b) of this Agreement.

9. Down Payment upon Signing.

In consideration of the licenses granted by TANABE to VIVUS hereunder, VIVUS shall make the following payments to TANABE:

- (a) a non-refundable and non-creditable signing down payment to TANABE of (\*\*\*), within one (1) week after the later effective date of signature of this Agreement by both Parties; and
- (b) a non-refundable and non-creditable payment to TANABE of (\*\*\*), by February 28, 2001, subject to VIVUS satisfaction of the results of (i) its due diligence review of the INFORMATION provided by TANABE and (ii) Dr. (\*\*\*) experiments with T-1790 (VIVUS shall provide the results of Dr. (\*\*\*) experiments with T-1790 to TANABE). If VIVUS is not satisfied with such results or fails to make such payment, this Agreement shall terminate.

10. Milestone Payments.

In further consideration of the licenses granted by TANABE to VIVUS hereunder, VIVUS shall make the following non-refundable and non-creditable milestone payments to TANABE as such milestones are achieved:

- (a) For the ORAL PRODUCT for male erectile dysfunction:
  - (1) (\*\*\*), upon the enrollment of the first patient in the first PHASE II CLINICAL STUDIES in the TERRITORY.
  - (2) (\*\*\*), upon the enrollment of the first patient in the first PHASE III CLINICAL STUDIES in the TERRITORY,
  - (3) (\*\*\*), upon the first submission of a NDA (or any equivalent license in the TERRITORY),
  - (4) (\*\*\*), upon obtainment of REGULATORY APPROVAL in the United States, and
  - (5) (\*\*\*) upon obtainment of the first REGULATORY APPROVAL in any MAJOR EUROPEAN COUNTRY.
- (b) For the NON-ORAL PRODUCT for male erectile dysfunction:
  - (1) (\*\*\*), upon the enrollment of the first patient in the first PHASE II CLINICAL STUDIES in the TERRITORY,
  - (2) (\*\*\*), upon the first submission of a NDA (or any equivalent license in the TERRITORY), and
  - (3) (\*\*\*), upon obtainment of REGULATORY APPROVAL in the United States, and (\*\*\*) upon obtainment of the first REGULATORY APPROVAL in any MAJOR EUROPEAN COUNTRY.
- (c) For the ORAL PRODUCT for female sexual dysfunction:
  - (1) (\*\*\*), upon the first submission of a NDA (or any equivalent license) in the TERRITORY, and
  - (2) (\*\*\*) upon obtainment of REGULATORY APPROVAL in the United States, and (\*\*\*) upon obtainment of the first REGULATORY APPROVAL in any MAJOR EUROPEAN COUNTRY.

- (d) For the NON-ORAL PRODUCT for female sexual dysfunction:
  - (1) (\*\*\*) upon the enrollment of the first patient in the first PHASE III CLINICAL STUDIES in the TERRITORY,
  - (2) (\*\*\*) upon the first submission of a NDA (or any equivalent license) in the TERRITORY, and
  - (3) (\*\*\*) upon obtainment of REGULATORY APPROVAL in the United States, and (\*\*\*) upon obtainment of any REGULATORY APPROVAL in any MAJOR EUROPEAN COUNTRY.
- (e) (\*\*\*) when the total NET SALES during any CALENDAR YEAR for the ORAL PRODUCT sold by VIVUS, its AFFILIATES and its SUBLICENSEES exceed (\*\*\*) the amount of which shall be calculated using the currency conversion method consistent with the method set forth in Section 12.3.

VIVUS shall notify TANABE in writing within thirty (30) days upon the achievement of each milestone, such notice to be accompanied by the appropriate milestone payment. It is understood and agreed that each milestone payment in Section 10 (a) through (e) above shall be paid only once upon achievement of the particular milestone.

11. Supply Price.

11.1 Supply Price for ORAL PRODUCT. The supply price (FCA place of manufacture, Incoterms 2000) to be paid to TANABE by VIVUS for its commercial use of the BULK DRUG TABLETS for ORAL PRODUCT shall be calculated based on a percentage of annual (CALENDAR YEAR basis) total NET SALES in the TERRITORY according to the following:

Annual Total NET SALES in the TERRITORY -----	Supply Price -----
For the portion up to (***)	(***) of the NET SALES
For the portion in excess of (***) and up to (***)	(***) of the NET SALES
For the portion in excess of (***)	(***) of the NET SALES

11.2 Supply Price for NON-ORAL PRODUCT. The supply price (FCA place of manufacture, Incoterms 2000) to be paid to TANABE by VIVUS for its commercial use of the BULK DRUG SUBSTANCE for the formulation and manufacture of NON-ORAL PRODUCT shall be calculated based on a percentage of annual (CALENDAR YEAR basis) total NET SALES in the

TERRITORY according to the following:

Annual Total NET SALES in the TERRITORY -----	Supply Price -----
For the portion up to (***)	(***) of the NET SALES
For the portion in excess of (***) and up to (***)	(***) of the NET SALES
For the portion in excess of (***)	(***) of the NET SALES

- 11.3 Revision of Supply Price. Notwithstanding the foregoing Section 11.1 and 11.2, in case either Party cannot obtain a reasonable profit from the PRODUCT business, the Parties shall discuss in good faith to revise the supply price, taking into consideration (i) their MANUFACTURING COST, (ii) NET SALES per one (1) treatment and (iii) the balance of the profit of the Parties, provided however that, in no event TANABE shall be obliged to supply the BULK DRUG TABLETS or the BULK DRUG SUBSTANCE at the price less than their MANUFACTURING COST.
- 11.4 Retroactive Adjustment. The supply price shall be determined based on the average NET SALES of the immediately preceding CALENDAR QUARTER; provided, however, that if the actual amount of the NET SALES is not available, an estimated NET SALES shall be used for the calculation of the supply price and the necessary retroactive adjustment shall be made immediately after the actual amount of the NET SALES becomes available.
- 11.5 Cash Remittance. For all purchases of the BULK DRUG SUBSTANCE from TANABE, VIVUS shall pay to TANABE by means of cash remittance (by bank transfer) payable within sixty (60) days after the date of TANABE's invoice.
12. Payment of the Down Payment, Milestone Payments and Supply Price Payments. The following Sections 12.1 through 12.7 shall apply to the supply price payments under Article 11, and the applicable parts of Sections 12.1 through 12.7 shall apply also to the down payment under Article 9 and milestone payments under Article 10:
- 12.1 Report of Sales Amount. Within sixty (60) days from the end of each CALENDAR QUARTER, VIVUS shall send TANABE the reports of such CALENDAR QUARTER describing the invoiced sales amount of the PRODUCT and the NET SALES in such CALENDAR QUARTER along with its calculation. VIVUS shall keep accurate records in sufficient detail to enable any payment payable hereunder to be determined.

- 12.2 Payment Account. All payments including down payment, milestone payments and supply price payment shall be made by wire transfer, if possible, to an account designated by TANABE from time to time; provided, however, that in the event TANABE fails to designate such account, VIVUS may remit such payments to TANABE to the address applicable for the receipt of notices hereunder; provided, further, that any notice by TANABE of such account or change in such account, shall not be effective until thirty (30) days after receipt thereof by VIVUS, except for the initial down payment under Article 9 which shall be notified to VIVUS reasonably prior to or upon the later effective date of signature of this Agreement by both Parties;.
- 12.3 Currency. The supply price payment shall be made in United States Dollars or any successor currency. The method of currency conversion from local currency into United States Dollars shall be made by using the exchange rate for the purchase of United States Dollars reported by the Wall Street Journal on the last business day of the CALENDAR QUARTER to which such payments relate.
- 12.4 Right to Audit. TANABE shall have the right, upon prior notice to VIVUS, not more than once in any CALENDAR YEAR, through an independent certified public accountant selected by TANABE and acceptable to VIVUS, which acceptance shall not be unreasonably refused, to have access during normal business hours to those records of VIVUS as may be reasonably necessary to verify the accuracy of the reports required to be furnished by VIVUS pursuant to Section 12.1. If such independent certified public accountant's report correctly shows any underpayment of supply price by VIVUS, VIVUS shall remit to TANABE within thirty (30) days after VIVUS' receipt of such report:
- (a) the amount of such underpayment;
  - (b) interest on the underpayment which shall be calculated pursuant to Section 12.5; and
  - (c) the reasonably necessary fees and expenses of such independent certified public accountant performing the audit, if such underpayment exceeds five (5%) percent of the total supply price payment owed for the CALENDAR YEAR then being reviewed. Otherwise, TANABE's accountant's fees and expenses shall be borne by TANABE. Any overpayment of supply price payment shall be fully creditable against future supply price payment payable in any subsequent periods. Upon the expiration of thirty-six (36) months following the end of any CALENDAR YEAR, the calculation of supply price payment payable with respect to such CALENDAR YEAR shall be binding and conclusive on TANABE and VIVUS, unless an audit for such CALENDAR YEAR is initiated before expiration of such thirty-six (36) months.

Should VIVUS not agree with the report, VIVUS may submit its own report within ninety (90) days of receiving TANABE's report. If the two reports differ, the Parties shall meet and discuss how to resolve the discrepancy. If the Parties fail to reach agreement, the Parties will resolve the dispute as recited in Article 28.

- 12.5 Overdue Payment. In the event any payment due hereunder is not made when due, the payment shall accrue interest (beginning on the date such payment is due) calculated at the rate of one (1%) percent per month and such payment when made shall be accompanied by all interest so accrued.
- 12.6 Record of Sales. Notwithstanding anything herein to the contrary, VIVUS shall keep, or cause to be kept, records of the sales of the PRODUCT under this Agreement for a period of seven (7) years after the expiration of each CALENDAR YEAR. Upon the request by TANABE, VIVUS shall supply TANABE with such records which may be submitted to the tax authority, and shall give TANABE any reasonable assistance in relation thereto.
- 12.7 Taxes. TANABE shall pay any and all taxes levied on account of down payment, milestone payments and supply price payments it receives under this Agreement. If laws or regulations require that taxes be withheld, VIVUS will (i) deduct those taxes from the otherwise remittable payments, (ii) timely pay the taxes to the proper taxing authority, and (iii) give TANABE any reasonable assistance, which shall include the provision of such documentation as may be required by the tax authority to enable TANABE to claim exemption from or obtain a repayment of or reduction of tax.

13. Inventory.

VIVUS shall maintain commercially reasonable quantities of the BULK DRUG SUBSTANCE and the PRODUCT. Such inventories shall be commercially reasonably sufficient to meet the market requirements.

14. Maintenance and Abandonment of Patent.

Each Party shall use its reasonable efforts to prosecute and maintain its respective patents worldwide (the TANABE PATENTS with respect to TANABE and the VIVUS PATENTS with respect to VIVUS); provided TANABE shall reimburse VIVUS' patent costs for prosecuting and maintaining the VIVUS PATENTS outside the TERRITORY, such reimbursement creditable against any payments due by TANABE under any license obtained pursuant to Section 2.5(b). TANABE shall promptly give notice to VIVUS of the grant, lapse, revocation, surrender, invalidation or abandonment of any TANABE PATENT. VIVUS shall promptly give notice to TANABE of the grant, lapse, revocation, surrender, invalidation or abandonment of any VIVUS PATENT. In the event that applicable law in any country of TERRITORY provides for the

extension of the term of any TANABE PATENT which TANABE is prosecuting or maintaining, TANABE shall apply for and use its reasonable efforts to obtain such an extension and VIVUS agrees to cooperate with TANABE in obtaining such extension. In the event that applicable law in any country of TERRITORY provides for the extension of the term of any VIVUS PATENT which VIVUS is prosecuting or maintaining, VIVUS shall apply for and use its reasonable efforts to obtain such an extension and TANABE agrees to cooperate with VIVUS in obtaining such extension.

15. Infringement

- 15.1 THIRD PARTY Infringement. If VIVUS or TANABE becomes aware of any activity that it believes represents a substantial infringement of the TANABE PATENT, the Party obtaining such knowledge shall promptly advise the other of all relevant facts and circumstances pertaining to the potential infringement. VIVUS and TANABE shall thereafter consult and cooperate fully to determine a course of action, including but not limited to, the commencement of legal action to terminate any infringement of the TANABE PATENT. However, TANABE shall have the first right to initiate and prosecute such legal proceedings, at its own expense and in the name of TANABE, and to control the defense of any declaratory judgment action relating to the TANABE PATENT. VIVUS shall cooperate with TANABE in such effort, including being joined as a party to such action if necessary.
- 15.2 VIVUS Right to Pursue THIRD PARTY Infringers. If TANABE does not proceed, within sixty (60) days after receiving notice from VIVUS of a potential infringement of TANABE PATENT or within sixty (60) days after providing VIVUS with notice of such infringement, either (i) in terminating such infringement or (ii) in instituting an action to prevent continuation thereof, or if TANABE notifies VIVUS that it does not plan to terminate the infringement of TANABE PATENT or to institute any such action, then VIVUS shall have the right to do so. TANABE shall cooperate with VIVUS in such effort, including being joined as a party to such action if necessary.
- 15.3 Updating. Each Party shall keep informed of development in any action or proceeding relating to the TANABE PATENT or VIVUS PATENT including, to the extent permissible by law, the state of any settlement negotiations and the terms of any offer related thereto.
- 15.4 Damage Award or Settlement Payments. Any damage award or settlement payments made in connection with any action relating to infringement of TANABE PATENT in the TERRITORY, whether obtained by judgment, settlement or otherwise shall belong to the Party which instituted the action in accordance with this Article 15; provided, where such lawsuit or action was initiated by TANABE and VIVUS has joined and actively participated thereto, any recovery from such lawsuit shall be used to: (i) first reimburse TANABE for

expenses actually incurred by TANABE in connection with such lawsuit (including attorneys fees and professionals fees), (ii) then to reimburse VIVUS for expenses actually incurred by VIVUS in connection with such lawsuit (including attorneys fees and professionals fees), and (iii) then the remainder, if any, shall be allocated between TANABE and VIVUS on a (\*\*\*) basis respectively.

15.5 Defense of THIRD PARTY Claims.

- (a) If a THIRD PARTY asserts that a patent or other right owned by it is infringed by the development, manufacture, use or sale of any PRODUCT, VIVUS shall be solely responsible for defending against, or at its option settling, any such assertions at its cost and expense (so long as VIVUS has the right to sell such PRODUCT hereunder), excluding any claims subject to TANABE's defense obligations under the following Section 15.5(b).
- (b) If a THIRD PARTY asserts that a patent or other right owned by it is infringed by (i) the manufacture of any BULK DRUG SUBSTANCE or BULK DRUG TABLETS by or on behalf of TANABE, or (ii) the sale of any PRODUCT sold or transferred by or on behalf of TANABE outside the TERRITORY, TANABE shall be solely responsible for defending against, or at its option settling, any such assertions at its cost and expense, excluding any claims subject to VIVUS' defense obligations under the foregoing Section 15.5(a).
- (c) With respect to any claim of infringement alleged under this Section, the Parties shall meet and discuss the appropriate action to take to address such claim, including without limitation, (i) replacing or modifying the allegedly infringing PRODUCT, BULK DRUG SUBSTANCE OR COMPOUND or parts thereof, with other suitable and reasonably equivalent technology or parts so that they become non-infringing (ii) defending such action, or (iii) settling such action, including obtaining a license from a THIRD PARTY to manufacture, use or sell, as appropriate, such PRODUCT, BULK DRUG SUBSTANCE, or COMPOUND.

16. Warranties and Indemnification.

- 16.1 Warranties of Each Party. Each Party hereto represents to the other that it has the right to enter into this Agreement and to carry out all of the provisions hereof.
- 16.2 Encumbrances. TANABE expressly warrants and represents that it has no outstanding encumbrances or agreements, either written, oral, or implied, in connection herewith, and that it has not granted and will not grant during the term of this Agreement or any renewal hereof, any rights, license, consent or privilege that conflict with the rights granted herein. TANABE further represents and warrants, to the best of its knowledge as of the EFFECTIVE DATE, that (i) the TANABE PATENTS, TANABE KNOW-HOW and

INFORMATION are not currently being infringed by a THIRD PARTY, and (ii) that other than (\*\*\*) and (\*\*\*) and any corresponding patent application claiming priority thereto (excluding any new matter contained within such corresponding patent application), under which the patent owners may allege infringement, the development, manufacture, use and/or sale of the BULK DRUG SUBSTANCE, BULK DRUG TABLETS, COMPOUND and/or PRODUCT do not infringe any property rights of any THIRD PARTY.

- 16.3 Authorization. Each Party hereby warrants that the execution, delivery and performance of this Agreement has been duly approved and authorized by all necessary corporate or partnership actions of itself; does not require any shareholder or partnership approval which has not been obtained or the approval and consent of any trustee or the holders of any indebtedness of itself; does not contravene any law, regulation, rules or order binding on itself, and does not contravene the provisions of or constitute a default under any indenture, mortgage, contract or other agreement or instrument to which it is a signatory.
- 16.4 No Liability for Consequential Damages and Limitation of Liability. Neither Party shall be liable to the other for incidental or consequential damages arising out of or related to the subject matter of this Agreement.
- 16.5 Indemnification.
- (a) Subject to compliance by TANABE or its AFFILIATES with its obligations set forth in Section 16.6, VIVUS shall defend, indemnify, and hold harmless TANABE, its AFFILIATES and their respective directors, officers, employees and agents (each a "TANABE Indemnitee"), from and against any and all THIRD PARTY claims, demands, losses, liabilities, expenses, and damages including reasonable attorneys' fees (collectively, the "Liabilities") which such TANABE Indemnitee may suffer, pay, or incur to the extent resulting from (i) any breach of a representation, warranty, covenant or obligation of VIVUS under this Agreement, (ii) any negligent or more culpable act of VIVUS under this Agreement, or (iii) any and all personal injury (including death) and property damage to the extent caused by development, manufacture, use or marketing of BULK DRUG TABLETS, BULK DRUG SUBSTANCE, COMPOUND, and/or PRODUCT by VIVUS, its AFFILIATES or their SUBLICENSEES, excluding, however, any Liabilities subject to TANABE's indemnification obligation under the following Section 16.5(b). VIVUS' obligations under this Section 16.5(a) shall survive the expiration or termination of this Agreement for any reason.
- (b) Subject to compliance by VIVUS with its obligations set forth in Section 16.6, TANABE shall defend, indemnify and hold harmless VIVUS, its AFFILIATES and their SUBLICENSEES and their respective directors, officers, employees and agents (each a "VIVUS Indemnitee"), from and

against any and all Liabilities which such VIVUS Indemnitee may suffer, pay or incur to the extent resulting from (i) any breach of a representation, warranty, covenant or obligation of TANABE under this Agreement, (ii) any negligent or more culpable act of TANABE under this Agreement, or (iii) any and all personal injury (including death) and property damage to the extent caused by development, manufacture, use or marketing of BULK DRUG TABLETS, BULK DRUG SUBSTANCE, COMPOUND and/or PRODUCT by TANABE, its AFFILIATES or their SUBLICENSEES, excluding, however, any Liabilities subject to VIVUS' indemnification obligation under Section 16.5(a) above. TANABE's obligations under this Section 16.5(b) shall survive expiration or termination of this Agreement for any reason.

- 16.6 Indemnification Procedures. In the event a Party intends to claim indemnification under Section 16.5 for itself or its indemnitee (the "Indemnitee"), such Party shall promptly notify the other Party (the "Indemnitor") in writing of any matter in respect of which the Indemnitee intends to claim such indemnification. The Indemnitee shall permit the Indemnitor, at its discretion, to settle any such matter and agrees to the complete control of such defense or settlement by the Indemnitor; provided, however, that such settlement does not adversely (i) affect the Indemnitee's rights under this Agreement or (ii) impose any material obligations on the Indemnitee in addition to those set forth herein in order for Indemnitee to exercise rights under this Agreement. No settlement of any such matter which materially and adversely affect the Indemnitee's rights under this Agreement or impose any material obligations on the Indemnitee in addition to those set forth herein in order for Indemnitee to exercise rights under this Agreement may be made by the Indemnitor without the prior written consent of the Indemnitee. The Indemnitee shall not be responsible for any legal fees or other costs incurred other than as provided herein. The Indemnitee and its directors, officers and employees shall cooperate fully with the Indemnitor and its legal representatives in the investigation and defense of any matter covered by the applicable indemnification. The Indemnitee shall have the right, but not the obligation, to be represented by counsel of its own selection and at its own expenses in connection with any matter that is subject to indemnification. It is understood that only a Party may claim indemnity under this Section 16 (on its own behalf or on behalf of its Indemnitee), and other TANABE Indemnitees and VIVUS Indemnitees may not directly claim indemnity hereunder.

17. TRADEMARK.

VIVUS shall be responsible for the selection and registration of all TRADEMARKS which it employs in connection with PRODUCT in the TERRITORY. VIVUS shall obtain a written consent of TANABE prior to the registration of TRADEMARK, which consent shall not be unreasonably withheld or delayed. TANABE shall have the right to register and use the same

TRADEMARK exclusively and free of charge in connection with the marketing of the ORAL PRODUCT outside the TERRITORY; provided, such TRADEMARK shall be used by TANABE solely with the ORAL PRODUCT and not with any other product. It is understood and agreed that additional marks may be used with the PRODUCTS, including without limitation the VIVUS mark, and that such additional marks shall not be subject to the assignment provisions of Sections 21.1 or 21.2.

18. Confidentiality and Publication.

18.1 Confidentiality. Each Party hereto shall treat all the information received from the other Party in connection with this Agreement (including the information disclosed before the execution of this Agreement) as confidential, not to be disclosed to any other person, company or firm and not to be used for any other purpose than for the purpose of this Agreement either before or after the expiration or termination of this Agreement except the following information:

- (a) information which at the time of the disclosure is part of the public knowledge;
- (b) information which, after the disclosure, becomes part of the public knowledge by publication or otherwise, except through acts or omissions of the receiving Party;
- (d) information which the receiving Party can establish by competent proof was in the receiving Party's possession at the time of the disclosing Party's disclosure;
- (e) information which was otherwise developed independently by the receiving Party, as demonstrated by written records kept in the ordinary course of business; and
- (e) information which the receiving Party lawfully receives from a THIRD PARTY; provided, however, that such information was not obtained by said THIRD PARTY directly or indirectly from disclosing Party under a confidential obligation.

Notwithstanding the foregoing, each Party, may disclose confidential INFORMATION to the governmental or other regulatory authorities to the extent that such disclosure (i) is necessary for the filing, prosecution and enforcement of patents, or authorizations to conduct preclinical studies, CLINICAL STUDIES or POST REGISTRATION STUDIES to commercially market PRODUCT, provided such Party is then otherwise entitled to engage in such activities in accordance with the provisions of this Agreement, or (ii) is legally required.

18.2 Publication. Each Party shall submit to the other Party any proposed scientific

publication containing confidential INFORMATION of the other Party at least thirty (30) days in advance of submission thereof for the public disclosure to allow that Party to review such proposed disclosure. The reviewing Party shall promptly review such proposed scientific publication and make any objections that it may have to the publication of the confidential INFORMATION contained therein. Should the reviewing Party make an objection to the publication of the confidential INFORMATION, then the Parties will discuss the merits of publishing; provided, however, that in any case, no publication of confidential INFORMATION shall take place under this Section 18.2 without the disclosing Party's prior written approval thereof or unless the obligations of confidentiality as to such confidential INFORMATION shall be waived pursuant to Section 18.1 or disclosure of confidential INFORMATION is authorized under Section 18.1. Parties agree that review of scientific abstracts will take place on an expedited basis, with the reviewing Party having seven (7) business days to submit comments and make objections.

- 18.3 Publicity. Each Party agrees that the other Party may issue a press release concerning the entering into of this Agreement, with the content of such releases to be approved by the non-issuing Party (which consent shall not be unreasonably withheld or delayed). In all other respects, except as required by law, neither Party shall publicly use the name of the other Party or any logos or symbols associated with the other Party without the prior written approval of such other Party. Except as provided above, such as wherein VIVUS is permitted to use TANABE's name and logo in connection with the PRODUCT neither Party shall publicly disclose the terms of this Agreement or issue any publicity release with regard thereto unless expressly authorized to do so by the other Party. Once a particular disclosure has been approved for disclosure, either Party may make disclosures which do not differ materially therefrom without any need for further consents.

19. Reports on ADVERSE DRUG REACTION

Within one-hundred and eighty (180) days after the EFFECTIVE DATE, the STEERING COMMITTEE shall meet and prepare a plan for sharing and submitting INFORMATION and filing reports to various governmental agencies on PRODUCT under CLINICAL STUDIES and marketed PRODUCT, including without limitation safety related information and ADVERSE DRUG REACTION information.

20. Term and Termination

- 20.1 Term. On a country-by-country and on a PRODUCT-by-PRODUCT basis, the term of this Agreement shall continue until the later of (i) ten years after the DATE OF FIRST SALE for a particular PRODUCT, or (ii) expiration of the last to expire patents within the TANABE PATENTS covering such PRODUCT in such country.

- 20.2 Termination due to Breach. Without prejudice to any remedy or claims it may have against the other Party for material breach of this Agreement, either Party shall be entitled to terminate this Agreement by giving the other Party at least thirty (30) days' prior notice in writing if the other Party should materially breach any of the provisions or conditions of this Agreement and if after having been given a written warning the other Party should fail to discontinue or should fail to make good such material breach within ninety (90) days after receipt of the warning.
- 20.3 Termination due to Insolvency or Bankruptcy. In the event of insolvency or bankruptcy of either Party or appointment of a trustee or receiver for either Party, it shall immediately notify the other Party to that effect. In any such event, the Party so notified shall have the right to terminate this Agreement at any time.
- 20.4 Permissive Termination. In the event that a PRODUCT is deemed to be (i) insufficiently effective or insufficiently safe relative to other PDE5 INHIBITOR compounds based on published information, or (ii) not economically feasible to develop due to unforeseen regulatory hurdles or costs as measured by standards common in the pharmaceutical industry for this type of product, VIVUS shall have the right to terminate this Agreement with respect to such PRODUCT.

21. Rights and Duties on Expiration and Termination

- 21.1 Rights and Duties on Expiration. Following Sections shall apply to the case of expiration of this Agreement, pursuant to Section 20.1:
- (a) VIVUS agrees to transfer to TANABE, free of charge, its ownership of the TRADEMARK as VIVUS used for the ORAL PRODUCT, provided, however, that the Parties shall, upon request of VIVUS, execute a simple TRADEMARK license agreement under which VIVUS continues to use on an exclusive basis said TRADEMARK for the ORAL PRODUCT in the TERRITORY as long as VIVUS continues the marketing of the ORAL PRODUCT in the TERRITORY. Under such TRADEMARK license agreement, VIVUS shall pay to TANABE a royalty equal to two percent (2%) of the NET SALES of the ORAL PRODUCT marketed with such TRADEMARK for the first three (3) years following expiration of this Agreement, and a royalty equal to one percent (1%) of the NET SALES of the ORAL PRODUCT marketed with such TRADEMARK for two additional years thereafter. Thereafter, VIVUS shall be free to use such TRADEMARK in conjunction with the marketing and sale of ORAL PRODUCTS free of charge.
- (b) Upon expiration of this Agreement in a particular country, VIVUS shall have a perpetual, irrevocable, fully paid-up license to practice the TANABE KNOW-HOW in such country.

21.2 Rights and Duties on Termination. Following Sections shall apply to the case of termination of this Agreement pursuant to Sections 20.2 and 20.3 due to VIVUS' breach or insolvency or to the case of termination of this Agreement with respect to a particular PRODUCT pursuant to Section 20.4 (except, the following Sections shall only apply, as applicable, with respect to such particular PRODUCT and not with respect to any other PRODUCT):

- (a) VIVUS agrees to transfer to TANABE, free of charge, its ownership of the TRADEMARK as VIVUS used for the PRODUCT, and VIVUS shall immediately stop using such TRADEMARK. Thereafter, VIVUS shall not use any trademark which is similar to or confusing with the TRADEMARK.
- (b) VIVUS shall, upon TANABE's request, if applicable, provide to TANABE or its nominee, free of charge, all the DRUG APPROVAL APPLICATION and REGULATORY APPROVAL for the PRODUCTS (in the event VIVUS has not applied for DRUG APPROVAL APPLICATION or REGULATORY APPROVAL for a particular PRODUCT in a particular country, VIVUS shall provide to TANABE all the INFORMATION VIVUS reasonably would have included in such application or approval). TANABE shall only use the VIVUS INFORMATION contained with such DRUG APPROVAL APPLICATION or REGULATORY APPROVAL for applying for and obtaining regulatory approval for the PRODUCTS, and not for any other use.
- (c) TANABE or its nominee(s) shall have the optional rights to take over all or any part of the remaining stocks of the BULK DRUG SUBSTANCE and the PRODUCT in the warehouses and factories of VIVUS at such prices as may be agreed between the Parties. VIVUS shall not thereafter market or manufacture any PRODUCT covered by this Agreement. In case TANABE or its nominee(s) do not exercise the optional rights to take over the stocks of the BULK DRUG SUBSTANCE and the PRODUCT pursuant to this Section 21.2(c), VIVUS shall have the right to sell the residual salable or usable stocks of the PRODUCT for the term of six (6) months after the termination of this Agreement, provided that the payment defined in this Agreement for such remaining stocks shall be made accordingly.

21.3 Rights and Duties on Expiration and Termination. The following Sections shall apply to the case of expiration under Section 20.1 and termination under Sections 20.2, 20.3, and 20.4 of this Agreement:

- (a) Neither Party shall be entitled to claim from the other Party any sum in respect of compensation whether for loss of profits or otherwise for the cessation of the benefits of this Agreement, and either Party expressly waives all rights (if any) which it may have to any such compensation.

- (b) Termination of this Agreement for any reason shall not release any Party hereto from any liability which, at the time of such termination, has already accrued to the other Party or which is attributable to a period prior to such termination nor preclude either Party from pursuing any rights and remedies it may have hereunder or at law or in equity with respect to any breach of, or default under, this Agreement. It is understood and agreed that monetary damages may not be a sufficient remedy for any breach of this Agreement and that the non-breaching Party may be entitled to injunctive relief as a remedy for any such breach..
- (c) Except as required to exercise their respective surviving rights as set forth in Sections 20.4 or 21.3(d), each Party shall surrender to other Party all written INFORMATION of the other Party, except those which have to be retained by such Party according to the laws or regulations, and shall not thereafter use or disclose any confidential INFORMATION of the other Party.
- (d) Sections 2.5, 12.1, 12.4, 12.5, 12.6, 16.5, and 20.1, and Articles 1, 18, 19, 21, 24, 26, 27, 28, 29, 30, 31, 32 and 33 and such provisions hereof as are required for the interpretation or enforcement of those Articles and Sections, shall survive and remain valid thereafter. Except as provided in this Section 21.3 (d) all other provisions of this Agreement shall terminate upon the expiration or termination of this Agreement.

22. TANABE Change in Control.

In the event TANABE Change in Control occurs during the term of this Agreement, VIVUS shall have the right, exercisable upon written notice to TANABE delivered at any time within sixty (60) days after the effective date of such TANABE Change in Control, to eliminate from this Agreement, TANABE's right to co-promote the PRODUCT in the TERRITORY as provided in Section 2.4. For purposes of this Agreement, "TANABE Change in Control" shall mean any transaction or series of related transactions by which a THIRD PARTY pharmaceutical company acquires or becomes the beneficial owner of (i) fifty percent (50%) or more of the outstanding voting securities of TANABE or the surviving entity, whether by merger, consolidation, reorganization, tender offer or other similar means, or (ii) all or substantially all of the assets of TANABE.

23. VIVUS Change in Control

In the event VIVUS Change in Control occurs during the term of this Agreement and the policy, strategy or priority of VIVUS relating to the DEVELOPMENT WORK or the marketing of the PRODUCT has been or is reasonably expected to materially fail to meet its obligations as provided in Article 5 and 6, TANABE shall have the right, exercisable upon written notice to VIVUS delivered at any time within four (4) months after the effective date of such VIVUS Change in Control, to terminate this Agreement. For purposes of this Agreement, "VIVUS

"Change in Control" shall mean any transaction or series of related transactions by which a THIRD PARTY pharmaceutical company acquires or becomes the beneficial owner of (i) fifty percent (50%) or more of the outstanding voting securities of VIVUS or the surviving entity, whether by merger, consolidation, reorganization, tender offer or other similar means, or (ii) all or substantially all of the assets of VIVUS.

24. Assignment and Transfer

- 24.1 Either Party may, at its sole discretion, but with reasonable prior notice to the other Party, designate and cause its AFFILIATE to perform all or part of its obligations under this Agreement or to have the benefit of all or part of its rights under this Agreement. In any such event, the name "TANABE" or "VIVUS" appearing herein shall be deemed to be the name of such AFFILIATE to the extent necessary to carry out the intent of this Section 24.1, and the performance of the obligations of such AFFILIATE shall be deemed guaranteed by the Party which has made such designation. In addition to the foregoing, either Party may assign this Agreement, without the consent of the other Party to a party that acquires all or substantially all of its business or assets, whether by merger, acquisition, sale or otherwise.
- 24.2 This Agreement shall be binding upon and inure to the benefit of TANABE and VIVUS and their successors or assignees, provided that any such successor or assignee shall have acquired all or substantially all of the stock or assets of the predecessor by merger, purchase, or otherwise. Otherwise, the rights and obligations set forth in this Agreement shall be not assignable (except to the limited extent provided in the foregoing Section 24.1) without the prior consent in writing of the other Party hereto, such consent not to be unreasonably withheld.

Any acquiring entity shall provide to the non-assigning party, a written commitment that it will use the same efforts, commensurate with the assigning party's efforts, to fully perform under this Agreement, including without limitation, to adhere to the current DEVELOPMENT PLAN (timing, budget and milestones) then in effect.

25. Force Majeure.

Neither Party shall be responsible for a failure or delay in performance of any of its obligations hereunder due to force majeure such as war, insurrection, strikes, acts of God, governmental action, or any other contingency beyond its control. However, the Party which is affected by any force majeure shall contact the other Party for discussion of possible emergency measures.

26. Notice.

Any and all notices required to be given under this Agreement shall be made by registered airmail and shall be addressed to the Parties at their respective offices

first above referred to, except that either Party may change such office by notice in accordance with this Article 26.

27. Governing Law.

This Agreement and any dispute, including without limitation any arbitration, arising from performance or breach hereof shall be governed by and construed and enforced in accordance with the following: (i) if a dispute is filed in court or in arbitration by VIVUS, the laws of Japan shall govern such dispute, and (ii) if a dispute is filed in court or in arbitration by TANABE, the laws of the state of California shall govern such dispute, in each case without reference to conflicts of law principles.

28. Arbitration.

All disputes, controversies, or differences which may arise between the Parties, out of or in relation to or in connection with this Agreement or the breach thereof, shall be finally settled by arbitration pursuant to the then obtaining Rule of Arbitration of the International Chamber of Commerce, by which each Party hereto agrees to be bound. Such arbitration shall be held in Osaka, Japan, if initiated by VIVUS, and in Palo Alto, California if initiated by TANABE. The Parties shall, however, attempt in good faith to amicably settle the disputes, controversies or differences by negotiations before having recourse to the arbitration procedure. It is understood and agreed that the filing by a Party of an action that is subject to this Section, whether in court or in arbitration, shall constitute an "initiation" of arbitration. Each Party agrees that any such action filed in court shall be stayed pending the outcome of the related arbitration.

Notwithstanding the then obtaining Rule of Arbitration of the International Chamber of Commerce, any arbitration shall be conducted by a panel of three arbitrators (the "Panel"). Each Party shall have the right to appoint one (1) member to the Panel, with the third member of the Panel to be mutually agreed to by the two Panel members appointed by the Parties. All Panel members shall be selected from a pool of independent arbitrators. Each Party shall make its appointment within thirty (30) days of receipt of a written request by a Party to initiate arbitration, and the third Panel member shall be selected by the two Panel members with thirty (30) days of the selection of the first two Panel members. All arbitration proceedings, including without limitation the filing of any documents, papers, and/or motions relating thereto, shall be made in the English language. In the event of any dispute concerning the construction or meaning of such documents, papers and/or motions, reference shall be made only to such documents, papers and/or motions as written in English and not to any translation into any other language.

29. Authentic Text.

This Agreement is entered into in the English language. In the event of any dispute concerning the construction or meaning of this Agreement, reference

shall be made only to this Agreement as written in English and not to any translation into any other language.

30. Interpretation.

Unless expressly set forth, the use of the singular form of terms herein shall include the plural and the use of the plural form of terms herein shall include the singular. Headings are for reference only and shall not be used to interpret this Agreement.

31. No Waiver.

The failure of either Party to enforce any provision of this Agreement at any time shall not be construed as a present or future waiver of such or any other provision of this Agreement. The express waiver by either Party of any provision or requirement hereunder shall neither be deemed nor operate as a future waiver of such or any other provision or requirement.

32. Entire Agreement.

This Agreement represents the entire agreement and understanding, as of the EFFECTIVE DATE, between the Parties with respect to the subject matter hereof and shall supersede all prior agreements, negotiations, understanding, representations, statements, and writings between the Parties relating thereto. No modification, alteration, waiver or change in any term or provision of this Agreement shall be valid or binding upon the Parties unless made in writing and duly executed by each of the Parties.

33. Severability.

Any provision of this Agreement which is invalid or unenforceable shall be invalid or unenforceable only to the extent of such invalidity or unenforceability, and the validity or enforceability of any other provision of this Agreement shall not be affected. The Parties shall replace such invalidated or unenforceable provision by valid and enforceable provision which will achieve, to the extent possible, the economic, business and other purposes of the replaced provision.

34. Injunctive Relief.

Each Party acknowledges and agrees that without resorting to prior mediation or arbitration, either Party, in addition to any other remedies that may be available in law, in equity or otherwise, shall be entitled to seek temporary and permanent injunctive relief in order to enforce its rights under this Agreement, without the necessity of proving actual damages or the posting of any bond.

IN WITNESS WHEREOF, the Parties have caused this Agreement to be duly executed by their respective officers as of the EFFECTIVE DATE.

TANABE SEIYAKU CO., LTD.

VIVUS, INC.

/s/ Toshio Tanaka

/s/ Leland F. Wilson

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By: Toshio Tanaka  
Title: President and Chief  
Executive Officer  
Representative Director  
Date: January 21, 2001

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By: Leland F. Wilson  
Title: President and Chief Executive  
Officer  
Date: January 21, 2001

## Attachment:

Appendix-A = List of the TANABE PATENT which covers the COMPOUND as of the  
EFFECTIVE DATE

Appendix-B = DEVELOPMENT PLAN

Appendix-C = STEERING COMMITTEE Guidelines

Appendix-D = Manufacture of the BULK DRUG SUBSTANCE

Appendix-E = Draft SPECIFICATIONS

APPENDIX-A

LIST OF THE TANABE PATENT  
WHICH COVERS THE COMPOUND AS OF THE EFFECTIVE DATE

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APPENDIX-B

DEVELOPMENT PLAN  
[TO BE ATTACHED HERE]

APPENDIX-C  
STEERING COMMITTEE GUIDELINES

STEERING COMMITTEE shall be responsible for managing all aspects of the relationship between the Parties to the extent not set forth in this Agreement, including but not limited to: (i) reviewing study protocols and making decisions on any proposed changes to the agreed DEVELOPMENT PLAN; (ii) monitoring and assisting progress of DEVELOPMENT WORK according to the agreed DEVELOPMENT PLAN; (iii) assessing the results of the CLINICAL STUDIES and non-clinical studies, (iv) discussing and resolving any drug supply and regulatory issue and (v) monitoring and supervising marketing, publications and publicity strategies and plans, in the TERRITORY. The STEERING COMMITTEE may adopt and revise policies under which VIVUS shall manage the agreed DEVELOPMENT PLAN.

1. Composition.

Within one (1) month of the EFFECTIVE DATE, each Party shall, by notice hereunder to the other, appoint one (1) chief representative and one (1) project manager to serve on the STEERING COMMITTEE to the extent it has not already done so. Each chief representative shall represent each Party and be responsible for performing the objectives of the STEERING COMMITTEE. Each project manager shall maintain regular communications between the Parties, serving as each Party's liaison and shall be responsible for organizing a development sub-committee and a marketing sub-committee (collectively, "Sub-Committees"). Subject to the requirements of the preceding sentence, at any time during the term of this Agreement, either Party may, by notice hereunder to the other, change or replace any of its chief representative or project manager on the STEERING COMMITTEE as it sees fit. Each Party's Sub-Committees shall have that Party's scientific, technical and regulatory expertise relating to the DEVELOPMENT WORK, and marketing and business development expertise relating to the PRODUCT. In addition, the STEERING COMMITTEE may invite either Party's or outside non-voting experts as the need arises.

2. Meetings.

The STEERING COMMITTEE shall hold its first official meeting within one (1) month of the EFFECTIVE DATE unless otherwise agreed by the Parties. At this first (1st) meeting, the STEERING COMMITTEE shall decide the scheduling of meetings. The STEERING COMMITTEE shall meet at least two (2) times per year, at places and on dates selected by each Party in turn.

3. Voting.

Each Party shall have one (1) vote on the STEERING COMMITTEE. Upon unanimous vote (except as provided in Section 4 below) all decisions of the STEERING COMMITTEE shall be binding on the Parties.

#### 4. Dispute Resolution.

Both TANABE and VIVUS are mutually responsible for ensuring the success of this Agreement in accordance herewith. Therefore, TANABE and VIVUS hereby agree to frankly discuss and attempt to resolve in good faith any conflicts which arise in ways which will promote the continuing goodwill between the Parties. If the members of the STEERING COMMITTEE cannot resolve any disagreement after good faith attempts to resolve such disagreement in a commercially reasonable fashion, then either of the Parties may refer the disagreement to a personal face-to-face meeting between the head of Research and Development of TANABE (or nearest equivalent) and the head of Research and Development of VIVUS (or nearest equivalent). If such persons cannot resolve the disagreement within one (1) month after such personal face-to-face meeting, then VIVUS will cast the deciding vote taking due consideration of TANABE's opinion.

APPENDIX-D  
MANUFACTURE AND SUPPLY OF THE  
BULK DRUG SUBSTANCE AND BULK DRUG TABLETS

1. General Supply Terms.

The following terms are applicable to both supplies for development and commercial use. It is understood and agreed that for this Appendix D, the use of the term BULK DRUG SUBSTANCE shall mean the BULK DRUG SUBSTANCE and/or BULK DRUG TABLETS, as applicable.:

- 1.1 Order Forecast. At least eight (8) months prior to the beginning of each month, VIVUS shall provide to TANABE an order forecast for the supply during such month of the BULK DRUG SUBSTANCE.
- 1.2 Firm Order. VIVUS shall place with TANABE a firm order at least one-hundred and twenty (120) days before the desired shipping date. Such firm order shall fall within the range from ninety percent (90%) to one hundred and twenty percent (120%) of such order forecast. TANABE shall accept all such orders.
- 1.3 Form of Order. VIVUS' orders shall be made in writing and shall provide for shipment in accordance with reasonable delivery schedules. No terms contained in any firm order, order acknowledgment or similar standardized form shall be construed to amend or modify the terms of this Agreement and in event of a conflict, this Agreement shall control unless otherwise expressly agreed in writing.
- 1.4 Delivery. TANABE agrees to ship quantities of the BULK DRUG SUBSTANCE ordered in accordance with Paragraph 1.2 on or about (but not later than seven (7) business days after the specified date) the dates specified in VIVUS' firm orders. The BULK DRUG SUBSTANCE shall be delivered to a carrier designated by VIVUS (FCA Place of Manufacture, Incoterms 2000). The packaging for shipment shall be sufficiently protective toward the BULK DRUG SUBSTANCE.
- 1.5 Invoice. TANABE shall send a single invoice upon delivery of each lot of the BULK DRUG SUBSTANCE to VIVUS at the address to be specified by it in writing on its firm order.
- 1.6 Duty. Any duty incurred, imposed or levied after the shipping point of the BULK DRUG SUBSTANCE shall be borne solely by VIVUS. TANABE shall use reasonable efforts to cooperate with VIVUS in eliminating all duties.
- 1.7 Quality Control. In order to ensure the quality of the PRODUCTS, including maximizing the PRODUCT shelf life, the Parties shall meet and agree upon when BULK DRUG SUBSTANCE shall be delivered to VIVUS after their manufacture by TANABE.

## 1.8 Acceptance or Rejection of the BULK DRUG SUBSTANCE

- (a) VIVUS shall examine each lot of the BULK DRUG SUBSTANCE for compliance with SPECIFICATIONS and any damage, defects or shortage, not later than thirty (30) days of receipt thereof. If VIVUS believes that any of such lot does not comply with the SPECIFICATIONS or is defective or damaged, VIVUS shall promptly, but not later than said thirty (30) days after receipt of such lot, notify TANABE and, if appropriate, send a sample of such lot to TANABE. Failure of VIVUS to reject a lot of the BULK DRUG SUBSTANCE in the manner set forth above shall constitute acceptance thereof.
- (b) Any claim notified by VIVUS pursuant to preceding Paragraph 1.8(a) shall be accompanied by a report of analysis, including an adequate sample of such lot of the BULK DRUG SUBSTANCE analyzed, and shall be handled as hereafter set forth in this Paragraph 1.8.
- (c) Should VIVUS reject any lot of the BULK DRUG SUBSTANCE under Paragraph 1.8(a) and TANABE agrees that such rejection is justified, TANABE shall promptly reimburse VIVUS for the supply price payment invoiced and paid for such lot of the BULK DRUG SUBSTANCE or cancel the invoice (if not yet paid) and replace the shipment or remedy the deficiency promptly.
- (d) Should VIVUS reject any lot pursuant to Paragraph 1.8(a), and TANABE and VIVUS, after good faith negotiation, fail to agree that such rejection is justified, the Parties shall mutually agree on an independent THIRD PARTY to evaluate all documentation relating to such lot of the BULK DRUG SUBSTANCE, which include but not limited to, certificate of analysis, certificate of compliance and report of analysis, and other relevant INFORMATION developed by either or both of the Parties relating thereto to ascertain whether the rejection is justified. If the THIRD PARTY determines that VIVUS' rejection is justified, TANABE shall pay for the costs of the independent THIRD PARTY's review, and the rejected BULK DRUG SUBSTANCE shall be handled as described in preceding Paragraph 1.8(c). If the THIRD PARTY determines that VIVUS' rejection is not justified, VIVUS shall pay for the costs of the independent THIRD PARTY's review, and the rejected BULK DRUG SUBSTANCE shall be accepted by VIVUS.

## 1.9 Hidden Defect.

If a defect is found in any lot of the BULK DRUG SUBSTANCE shipped by TANABE, which could not reasonably be expected to have been found by diligent and adequate inspection by VIVUS pursuant to its obligations under the Paragraph 1.8(a), such as stability, and if such defect is claimed to TANABE within six (6) months from the date of the receipt thereof, any such claim by VIVUS shall be

handled pursuant to the Paragraphs 1.8(b), (c) and (d).

2. Manufacture.

- 2.1 SPECIFICATIONS. TANABE shall manufacture and package the BULK DRUG SUBSTANCE which conform to the SPECIFICATIONS. A draft of SPECIFICATIONS shall be attached to the Agreement as Appendix-E and may be modified from time to time by prior written agreement between TANABE and VIVUS.
- 2.2 CGMP Manufacture. TANABE shall carry out all manufacturing, packaging and quality control operations in accordance with the current requirements of United States and European Good Manufacturing Practice (the "CGMP"). TANABE shall maintain an appropriate manufacturing authorization and thus maintain adequate premises, equipment, knowledge, and experienced and competent personnel to perform the work in compliance with the CGMP applicable to the particular country within the TERRITORY. TANABE shall refrain from any activity which adversely affects the quality of the BULK DRUG SUBSTANCE.
- 2.3 Manufacturing Records. TANABE shall keep full and complete records of every production lot in accordance with generally accepted industry practices including, but not limited to, the lot production records for each lot supplied (hereinafter referred to as "Records").
- 2.4 Audit. VIVUS may, at periodic intervals, audit the TANABE operation to ensure that the principles of CGMP continue to be followed. TANABE shall inform VIVUS from time to time and whenever requested by VIVUS, of the location of the Records, and shall permit VIVUS' representatives, for the purpose of quality audit, to have all reasonable access to the Records, TANABE's manufacturing, warehousing, packaging and laboratory areas, during normal business hours, to the extent VIVUS notifies TANABE in writing reasonably prior to the audit. Should VIVUS, after its audit, notify TANABE of any deficiencies, TANABE shall provide VIVUS with a response with proposed corrective actions within thirty (30) days of such notice and then promptly thereafter rectify any deficiencies noted during the course of audit by VIVUS, provided TANABE agrees with VIVUS' comments, which agreement shall not be unreasonably withheld or delayed. In addition, VIVUS shall have the right to audit TANABE's Records and documentation as it relates to the manufacture of the BULK DRUG SUBSTANCE, during normal business hours, to the extent such audit is needed to comply with CGMP and any applicable regulatory requirements.
- 2.5. THIRD PARTY Manufacture. TANABE may sub-contract any work relating to the manufacture of the BULK DRUG SUBSTANCE, provided, however, the manufacturing so sub-contracted shall be subject to the same terms and conditions as recited herein including but not limited to the right to audit the Records and inspect facilities. VIVUS shall have the right to approve such sub-contractor prior

to the selection, in case such sub-contracting is related to the final stage of the manufacture of the BULK DRUG SUBSTANCE, which approval shall not be unreasonably withheld or delayed.

- 2.6. Regulatory Inspections. In case TANABE receives advance notice of any proposed inspection by regulatory agencies such as the FDA or EMEA of its facility involving the BULK DRUG SUBSTANCE, TANABE shall promptly notify VIVUS to that effect. In case the inspections conducted by such regulatory agencies involve the BULK DRUG SUBSTANCE, TANABE shall inform VIVUS of the summary of such results. At VIVUS' request, TANABE shall cooperate in the investigation of any query or complaint concerning the BULK DRUG SUBSTANCE, and TANABE agrees to permit VIVUS to review and comment upon any response to the inspection that TANABE shall submit prior to the response to the regulatory agencies. VIVUS' review and comment shall be made promptly upon the receipt of TANABE's informing the content of the response.
- 2.7. Testing. TANABE shall test or cause to be tested each lot of the BULK DRUG SUBSTANCE before delivery to VIVUS. Each test shall set forth the items tested, SPECIFICATIONS and test results in a certificate of analysis for each lot delivered to VIVUS under this Agreement. TANABE shall send such certificate of analysis together with a certificate of compliance along with the delivery of the BULK DRUG SUBSTANCE. TANABE warrants that such tests are conducted diligently, the level of which is no less strict than the standard used for other goods or products which are manufactured and sold by TANABE itself.
- 2.8. Packing and Marking. Each lot of the BULK DRUG SUBSTANCE shall be shipped in accordance with TANABE's standard operating procedure and in accordance with instructions and specifications provided by VIVUS and accepted by TANABE which acceptance shall not be unreasonably withheld or delayed. All shipments shall be accompanied by a packing slip which describes the articles, states the order number and shows the shipment destination. TANABE agrees to promptly forward the original bill of lading or other shipping receipt for each shipment of the BULK DRUG SUBSTANCE in accordance with VIVUS' instructions to the extent such instructions are reasonable.
- 2.9. Qualification/Validation. TANABE shall be responsible for ensuring that an appropriate qualification/validation data is generated for any changes in processes, test methods and SPECIFICATIONS. TANABE shall supply VIVUS with the proposed protocols for qualification/validation, in advance of work conducted, for VIVUS' approval which shall not be reasonably withheld or delayed. TANABE shall supply VIVUS with a copy of the qualification/validation report.
- 2.10. Compliance with Laws. TANABE shall observe and comply with all laws, ordinances, codes and regulations of government agencies which are applicable to the place where the manufacture of the BULK DRUG SUBSTANCE is carried

out. In no event, shall TANABE be forced to maintain its facility or manufacture the BULK DRUG SUBSTANCE in a manner which violates the applicable laws and regulations.

3. Representation and Warranties

- 3.1 Manufacturing Warranty. TANABE represents and warrants that the BULK DRUG SUBSTANCE manufactured by TANABE for VIVUS pursuant to the Agreement shall be manufactured in accordance with any applicable regulations pertaining to the CGMP.
- 3.2 No Warranty by TANABE. Except for the express warranty set forth in Paragraph 3.1 or otherwise set forth in the Agreement, TANABE grants no other warranties, express or implied, by statute or otherwise, regarding the BULK DRUG SUBSTANCE including their merchantability and their fitness for any use, and VIVUS shall defend, indemnify and hold harmless TANABE, its AFFILIATE's and their respective directors, officers, employees and agents, from any THIRD PARTY loss, claim, action, damage, expense or liability, including defense costs and attorneys' fees arising out of or related to the handling, possession or use of the BULK DRUG SUBSTANCE by VIVUS.

APPENDIX-E  
DRAFT SPECIFICATIONS

TENTATIVE SPECIFICATION AND TESTING METHODS OF BULK DRUG SUBSTANCE

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TENTATIVE SPECIFICATION AND TESTING METHODS OF BULK DRUG TABLETS

( \*\*\*)

## LIST OF SUBSIDIARIES

The following is a list of subsidiaries of VIVUS, Inc.

1. VIVUS International Limited, a wholly owned subsidiary of VIVUS, Inc.
2. VIVUS UK Limited, a wholly owned subsidiary of VIVUS International Limited
3. VIVUS BV Limited, a wholly owned subsidiary of VIVUS International Limited
4. VIVUS Ireland Limited, a wholly owned subsidiary of VIVUS International Limited

## CONSENT OF INDEPENDENT PUBLIC ACCOUNTANTS

As independent public accountants, we hereby consent to the incorporation by reference of our report dated January 18, 2001 included in this Form 10-K, into the Company's previously filed Registration Statements (File No's. 000-23490, 333-29939 and 333-57374) on Form S-8.

/s/ ARTHUR ANDERSEN LLP

San Jose, California  
March 26, 2001